HOUSE OF COMMONS

SOCIAL SERVICES COMMITTEE

Session 1986–87

PROBLEMS ASSOCIATED WITH AIDS

MINUTES OF EVIDENCE

Wednesday 25 March 1987

National Blood Transfusion Service

Dr Harold Gunson

Blood Products Laboratory

Dr Richard Lane, Mr B J Crowley,
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Professor Ian Kennedy

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WEDNESDAY 25 MARCH 1987

Members present:

Mrs Renée Short, in the Chair

Mr Roy Galley
Mr Ron Lewis
Sir David Price
Mr Nicholas Winterton
Mr Tim Yeo

Memorandum submitted by Dr Harold Gunson, Director, National Blood Transfusion Service

THE CONSEQUENCES OF AIDS FOR THE BLOOD TRANSFUSION SERVICE

Introduction

The Blood Transfusion Service collects blood from voluntary, non-remunerated donors and from the donations prepares red blood cell concentrates, platelets for the correction of bleeding in patients with platelet deficiency, cryoprecipitate which is a crude preparation of Factor VIII used for the treatment of some haemophilia patients and plasma, some of which is used for the treatment of patients and the remainder is sent for fractionation into plasma products. These products cannot be heat-treated, a process which can only be applied to certain fractionated plasma products. Therefore, other means need to be taken to protect patients from transmission of the virus following their transfusion.

It was some time after the first patient was diagnosed as suffering from AIDS that the transfusion of blood was implicated in the transmission of AIDS. A report appeared in the USA scientific literature in 1983 describing an infant transfused with blood and platelets during 1982 suffering from the disease. Since that time, in the UK there have been reports of 11 patients developing AIDS as a result of blood transfusions, of whom only four have been transfused in this country. A further 33 patients have developed HIV antibody believed to have developed as a result of blood transfusion, but have not yet developed the disease.

When it is considered that between two and 2.5 million blood donations have been collected each year in the UK since 1983, the incidence of AIDS or HIV infection from transfusion in this country is low. The reason for this could, arguably, be due to the action taken from the Transfusion Service and the responsible attitude taken by the blood donors in the UK.

The steps taken to protect the blood supply are described below:

1983–1985

An immediate priority for the Blood Transfusion Service was to discourage those donors who belonged to groups of persons who were particularly susceptible to developing AIDS from giving blood. In September 1983 the Department of Health and Social Security (DHSS) in conjunction with the Blood Transfusion Service (BTS) issued a leaflet for blood donors requesting that homosexuals with many partners, drug addicts (male and female) using injections and sexual partners of patients with AIDS not to give blood.

This leaflet was distributed to donors either by mail when they were called to give blood, or at the blood collection session. It was found that it was more acceptable for donors to receive the leaflet in their own home and apart from those donors who walked into blood collection sessions, the pattern for distribution of future leaflets has been through the mail.

As knowledge of the disease increased the leaflet required updating and in January 1985 a second leaflet to blood donors was issued widening the persons at risk from AIDS, including homosexual and bisexual men, male and female drug abusers who inject drugs and sexual contacts of persons in these groups. In this leaflet it was stated, also, that AIDS had occurred in some haemophilia patients treated with blood products and that there was evidence that people who lived in Haiti or Central Africa, particularly Zaire and Chad may be at risk.

There was recognition by staff at Regional Transfusion Centres that vigilance in asking donors whether they had read the AIDS leaflet was important. In no circumstances have donors been questioned with

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respect to sexual practices at the reception desk; such questions were referred to the Medical Officer on the blood collection session who interviewed the donor in confidence.

At one Centre, North West Thames, where the incidence of persons at risk of developing AIDS was higher than in any other region, donors attending the Central London Clinic were asked, additionally, to complete a questionnaire in confidence to indicate whether they would prefer their blood to be used for research purposes only. This procedure has subsequently been extended to all sessions carried out by this Centre.

1985–1987

During 1984 the causative virus for AIDS was isolated as the retrovirus, "human T-cell lymphotropic virus", Type III (HTLV III) or lymphadenopathy-associated virus (LAV), now known as HIV.

Although the tests for the virus itself are not possible, the antibody to the HIV virus is found in patients suffering from AIDS and is accepted as evidence of HIV infection. Various companies began the process of developing an anti-HIV test suitable for screening large numbers of blood samples and the first test systems became available in March 1985.

It would have been reasonable to expect that when the test for anti-HIV was available, the problems for the Blood Transfusion Service could be eliminated. Donations which were anti-HIV positive could be assumed to be infectious for AIDS and could be withdrawn prior to use. In the event, the introduction of the screening tests posed further problems both of an ethical and practical nature.

Initial development and assessment of the anti-HIV tests were undertaken in the USA and it became evident within a short time that the tests were prone to false positives. It was important, therefore that specific confirmatory tests were developed so that false positive reactive tests could be identified, since it would be very unfortunate if donors were interviewed on the basis of a false positive result.

Also, despite publicity by the Blood Transfusion Service to discourage persons in high-risk groups from donating blood, it was feared that some persons in these groups would present as donors as a convenient way of finding out their anti-HIV status. Although some positive reactive donations may have been eliminated, there was the danger that false negative reactions could be obtained from an infectious donor, rendering the blood supply less secure. Alternative test venues were required for persons other than blood donors who wished to have an anti-HIV test.

Between March and October 1985 a succession of events took place with close co-operation between the BTS and the DHSS. The available anti-HIV tests were evaluated by the Public Health Laboratory Service (PHLS) and two systems were recommended for use by the Transfusion Service. Both of these systems were evaluated in two Transfusion Centres and this study revealed important factors in the conduct of the tests, most importantly the need for independent controls. The PHLS has provided such controls which are still used in Transfusion Centres on a daily basis. Arrangements were made with the PHLS and the Middlesex Hospital for the performance of confirmatory tests on positive reactors. Alternative test venues were established by Regional Health Authorities and a training programme was instituted for the scientific and technical staff at Regional Transfusion Centres.

It was agreed that the initial counselling of blood donors confirmed as anti-HIV positive would be carried out by senior medical staff at Regional Transfusion Centres and these persons attended courses organised by St Mary's Hospital, Paddington.

Informed consent of blood donors requesting permission to carry out the test on their donation was not practical. A third leaflet was issued in September 1985 informing donors that their blood would be tested for the antibody to AIDS and they were asked to sign an agreement at the blood collection session to this effect.

In addition, it was stressed in the leaflet that those persons in risk groups with respect to AIDS should not donate blood. This was an important part of the overall strategy to maintain as secure a blood supply as possible.

With the financial assistance of the DHSS and the Medical Research Council (MRC), a collation of the results of anti-HIV tests on blood donors from all the Regional Transfusion Centres in the UK has been undertaken at the North Western Regional Transfusion Centre. To the end of January 1987 a total of 3.5 million donations have been screened for anti-HIV and 70 have been confirmed as positive. Of these donors, 60 are male and 10 female. Fifty-eight are in recognised risk categories for AIDS, six (five males and one female) deny being in risk categories and six have yet to be investigated.

The incidence of blood donations confirmed as anti-HIV positive is approximately one in 50,000. During the period October 1985 to January 1987 many donors may have given more than one donation and this figure does not reflect the incidence of anti-HIV positives in blood donors. From February 1986 the number of new donors, ie those persons donating for the first time, has been analysed and out of 430,000 new donors, 19 (17 male and two female) have been confirmed anti-HIV positive, an incidence of one in 25,000. Of the 19 anti-HIV positive new donors, 17 are in recognised risk categories for AIDS and two have yet to be interviewed.

The incidence of anti-HIV positive blood donors in the UK is amongst the lowest recorded in the World being less than that in the USA and many European Countries by a factor of 10, but is comparable with that in Scandinavia. Within the UK there is a geographical variation in the incidence of anti-HIV positive donors; more than one-half of those in England and Wales have been found by the three London Centres and approximately one-quarter were found in Scotland where the commonest risk category was intravenous drug abuse.

During this period of analysis it has been shown that on one occasion blood from a donor was tested in the period between the onset of infection and anti-HIV formation and this led to HIV infection in the recipients. A further possible instance is under investigation. An accurate estimate of the frequency of HIV infected donors who are antibody negative is difficult to obtain since scanty information is available about the length of time elapsing between infection and antibody development. From our results and theoretical considerations, it appears that the chances of this occurrence will be less than one in one million blood donations. This finding, however, highlights the importance of maintaining vigilance in excluding persons who are in risk categories from becoming blood donors.

Of those anti-HIV positive donors who attended as blood donors, the majority did not consider that they belonged to a risk category as defined in the leaflet. In many instances homosexual activity and drug abuse had taken place up to seven years earlier and was not being currently practised by the donor. It is hoped that the wording in a fourth leaflet issued in September 1986 will be effective in dissuading such persons from donating blood. In this leaflet the risk categories are defined as:

Men who have had sex with another man since 1978

A drug abuser who has injected drugs

A haemophiliac who has received unheated blood products

Anyone who has lived in or visited Africa, South of the Sahara and has had sex with men or women living there

Sexual contacts of people in these groups including single contacts as well as regular relationships

A further revision of this leaflet is in progress.

Autologous Transfusion and Directed Transfusions

Autologous transfusion, which is the donation of blood by a person prior to need so that he/she can receive their own blood should this be required, has become an increasingly frequent request during the past year.

It is important to recognise the limitations of this procedure. Storing this blood in the frozen state has very limited value since the cost and availability would be difficult problems to overcome. It may be possible for some patients to donate a maximum of two or three donations prior to planned surgery so that this blood could be stored for a maximum of 35 days and transfused to the patient. This applied to a relatively small group of patients probably less than five per cent undergoing such surgery. It is important that publicity for autologous transfusion does not lead donors to think that their services are no longer required, since it is certain that its use would not materially affect the work of the Transfusion Service.

The Regional Transfusion Directors have recently established a multi-disciplinary Working Party to investigate the use for autologous transfusions and to produce guidelines for its performance. Its report is expected in April 1987.

Directed Transfusions, that is family members donating blood for a relative needing a blood transfusion, have also been requested. The Transfusion Service has resisted these requests. The chances of blood group compatibility, logistical considerations and the fact that such donations may carry no less a risk than those currently collected are the reasons for this decision.

Final Comments

During the past few years the work of the BTS has come under public scrutiny as never before. Several

cases where transfusion-associated HIV infection has occurred have been highlighted by the media. This has led to a considerable fear in many patients who are about to enter hospital for a transfusion and those who have had transfusions in the past. Although one cannot state categorically that blood transfusions are absolutely safe, the chances of contracting HIV infection or AIDS from blood transfusion is extremely remote. The fact that only two patients receiving blood products from one donor have contracted HIV infection in the use of 3.5 million donations since anti-HIV testing was introduced illustrates this point. Whilst it can be said that the British Blood Transfusion Service is one of the safest in the world, it is only with continuing vigilance that this can be maintained.

The publicity with respect to AIDS has also led to a fear that AIDS may be contracted by giving blood. The media must bear some responsibility for this. In television programmes on AIDS, the statement that AIDS can be transmitted by blood has been followed by a picture of donors giving blood. There is no doubt that this may have been a factor in 1984 and 1985 which caused a loss of blood donors but during the past year there has been extensive publicity stating that blood donors cannot contract AIDS and it is doubtful whether this is now a significant factor. The most recent publicity on AIDS seems to have encouraged donors to come forward and although local shortages of blood may occur for various reasons, donor recruitment is now satisfactory.

Memorandum submitted by Dr R S Lane, Director, Blood Products Laboratory

THE MANUFACTURE OF THERAPEUTIC PRODUCTS FROM HUMAN PLASMA

SUMMARY

Blood Products Laboratory is responsible for the preparation of plasma proteins derived from voluntarily donated blood; the main products are factor VIII, factor IX, immunoglobulins and albumin. Currently, the NHS imports large quantities of factor VIII and albumin.

The new manufacturing facility, to be commissioned and opened in 1987, will enable England and Wales to achieve self-sufficiency in plasma protein products. Also there is the additional benefit of increased product security related to voluntarily donated plasma and BPL virus inactivation procedures.

Following the impact of AIDS, all plasma is tested at source for the HIV antibody as well as hepatitis B surface antigen. All BPL products, with the exception of immunoglobulins and a special fibrinogen preparation, are heated to inactivate viruses. Immunoglobulins have a twenty year safety record with respect to virus transmission.

The process changes necessary to effect the heat treatment of all products have involved redirection of research and development programmes. Fortuitously, the problems posed by HIV were resolved in a more detailed study to eliminate infectivity associated with non-A non-B hepatitis. After 22 months of clinical trial there are no established cases of virus transmission associated with 8Y. This virus inactivation process used in preparation of 8Y is currently the most stringent in use.

The new manufacturing facility, probably technologically the most advanced in the world, permits the achievement of self-sufficiency and processing according to best manufacturing practice. Its capability to respond to a future AIDS-like situation, or advances in the field, is dependent upon recognition of this national asset as a centre of excellence warranting investment to support growth in research and development as well as production. Such recognition will ensure the continued supply of products equal, or superior, to those available from international pharmaceutical organisations at minimal cost to the NHS.

INTRODUCTION

The Blood Products Laboratory (BPL) at Elstree is a unit of the Central Blood Laboratories Authority (CBLA) which, in turn, is a Special Health Authority responsible for the preparation of special fractions from human plasma entirely derived from blood or blood donors voluntarily donating to the National Blood Transfusion Service (NBTS).

The main facility is the Blood Products Laboratory at Elstree but there are subsidiary facilities at Oxford concerned with pilot-scale process development of human plasma protein fractions and production of products used in the management of uncommon blood coagulation disorders. Between them, the laboratories distribute fractions throughout the National Health Service and General Practitioner Services of England and Wales, thus requiring to meet the health care needs of approximately 50 million people.

The main products prepared from human plasma are factor VIII, used in the clinical management of haemophilia, and factor IX, used in the treatment of patients with haemophilia B; immunoglobulins are prepared for the treatment of patients with hereditary deficiencies and in the specific prophylaxis of rhesus sensitisation of rhesus negative mothers, protection against tetanus, hepatitis B, herpes zoster, chicken pox, rabies and measles. Human albumin is prepared in a number of forms and is used as a life support solution to replace blood volume after haemorrhage, burns, during major surgery and during therapeutic plasma exchange.

Up to the present, the limited capacity of fractionation has meant that only 20 per cent of the current requirements of haemophiliacs for factor VIII is met from BPL and, for similar reasons, it is estimated that the utilisation of albumin by the NHS exceeds national production by two to three times.

To remedy these deficiencies within modern stringent requirements for pharmaceutical control, a new production facility at Elstree commenced its planning stages in 1983, is now being commissioned and will be officially opened on 29 April 1987. The function of this new building will be to manufacture products from human plasma at a rate which provides self-sufficiency within the specified needs of health care services in England and Wales, the main priority being supply to the NHS. The CBLA is charged with finding a market for any plasma fractions that are in excess of NHS needs, to develop income which assists with offsetting the capital cost of the new production facility.

PLASMA THROUGHPUT

BPL is supplied with plasma collected by the NBTS. No whole blood or other cellular components are sent to BPL; thus all source material is strictly limited to voluntary donor origin of donors resident in the UK.

By 1984, plasma supply was 217,000 litres, of which 154,000 litres was fresh frozen plasma (FFP), that is plasma separated from whole blood within eighteen hours of donation and frozen to −40°C, or plasma obtained by plasmapheresis; 58,000 litres were plasma separated from outdated blood (TEP) and the remainder were specific plasmas containing special immunoglobulins.

Since 1984, plasma supply from NBTS has been steadily increased to meet ongoing manufacturing demands and to create a stockpile of FFP ahead of the commissioning of the new factory. Therefore, by 1986, input of FFP had increased to 300,000 litres and TEP had dropped to 32,000 litres. Total plasma input was 340,000 litres.

The new production facility requires 450,000 litres of FFP per annum and approximately 50,000 litres of time-expired and other source plasmas.

The accentuation on FFP relates to the use of this material for the preparation of factors VIII, IX and other coagulation proteins, none of which remain viable in plasma unless separated and frozen within hours of donation.

In summary, self-sufficiency in the new factory at Elstree increases plasma demand from 150,000 litres to 500,000 litres per annum and this demand is being met from the fourteen Regional Transfusion Centres of the NBTS.

It should be noted that the new BPL facility will be the largest, public-sector, non-commercial plasma fractionation centre in the world and falls within the top ten of all plasma fractionation facilities. Technologically, it is probably the most advanced in the world.

PRODUCT OUTPUT

BPL has met the NHS requirement of all products with the principal exceptions of factor VIII and albumin. Significant imports of factor VIII and albumin have been established over the past years. Information on the distribution and use of different factor VIII products within the Haemophilia Service is kept by the UK Haemophilia Centre Directors: for example, in 1985, the total *NHS* factor VIII concentrate used was 23 million international units against 51 million i.u. of purchased commercial factor VIII concentrate. Exceptionally, in 1985 and again in 1986, purchase of heat-treated commercial factor IX was introduced by some Haemophilia Centres in preference to NHS unheated factor IX—in 1985 NHS IX used was 9M i.u. against 4M i.u. of commercial factor IX. With the re-entry of NHS heat-treated factor IX, this limited trend has been reversed.

Until BPL capacity can match the requirements of self-sufficiency in the NHS, there will be continued importation of factor VIII and albumin with its associated problem of reduced control on procedures for

virus inactivation. The converse applies, namely after self-sufficiency outputs are reached at BPL, there will be products available to the NHS which carry the security embodied in the quality of voluntarily donated source plasma and BPL internal control of procedures for virus inactivation.

The relevance of this data with regard to the control of HIV infection was presented in the British Medical Journal of 19 July 1986, volume 293, page 175: this is the latest authoritative data which indicated that in haemophiliacs treated with NHS factor VIII alone between 1980 and 1984 and numbering some 428, out of 198 tested at the time of reporting 20 had become positive to HIV antibody, of which approximately three quarters were associated with an isolated incident in Scotland. The data supported the anticipated lower incidence of HIV transmission by factor VIII and other blood products sourced from NBTS plasma.

PRODUCT PROFILE

Attached to this memorandum is a list of products currently issued from BPL, indicating the extent of process modification for virus inactivation in each case. It can be seen that all products, with the exception of immunoglobulins for intramuscular injection and the special preparation of dried fibrinogen are heated either in the wet or dry state. Treatment in the wet state for 10 hours at 60°C has a track record of safety in albumin preparations for more than two decades. Treatment in the dried state for 72 hours at 80°C represents the most stringent dry heat treatment process currently in use worldwide: it is reported on in greater detail below.

FOCUS ON FACTOR 8Y

The development of this product details milestones in the BPL research and development programme aimed at eradication of virus transmission by all products. The stimulus for this programme was the need to inactivate hepatitis viruses in blood coagulation products, notably viruses associated with non-A non-B forms of hepatitis.

By 1981, awareness of the serious nature of non-A non-B hepatitis in haemophiliacs was shared by clinicians and BPL scientific staff alike. The risk of virus transmission by factor VIII and factor IX concentrates prepared from large pools of human plasma meant that all newcomers to treatment were likely to contract the infection between the first and fourth treatment.

At BPL an examination of procedures for virus inactivation in protein fractions was undertaken and the requirements to introduce heat treatment were established. The basis of the decision was the excellent track record of albumin pasteurised in the wet state for 10 hours at 60°C. With coagulation factors two parameters were defined, first heat treatment should take place in the freeze dried product, second a high purity product had to be developed without incurring unacceptable penalties in the form of loss of yield.

By March 1984, a high purity process had been defined and a Crown Record filed. By August 1984, the first small-scale preparation of the new factor 8Y was successfully concluded and a production batch was completed by November 1984. By this time, it was discovered that the new high purity 8Y could tolerate dry heat at levels which were above any other known product and were expected to inactivate non-A non-B hepatitis virus.

By January 1985, the 8Y process was satisfactorily transferred from the pilot laboratory to BPL and by March 1985 the first clinical infusion of product was successfully completed. At the same time a UK patent application for the process was filed. In April 1985, a clinical trial was initiated to determine safety against transmission of viruses causing non-A non-B hepatitis and producing sero-conversion against HIV.

The clinical trial of 8Y continues and after 22 months there have been no established cases of virus transmission causing non-A non-B hepatitis. The implication for the less robust HIV virus is total inactivation.

The heat treatment process for 8Y is performed with only a 5 per cent yield penalty in activity and the high purity 8Y process which has increased the potency of NHS factor VIII concentrate more than tenfold has been achieved with a loss of yield less than 15 per cent.

It should be noted that *each one per cent loss of yield of factor VIII in the new production facility is equivalent to the loss of £135,000 of product.*

Other products: since establishing the heat treatment process with 8Y, it has been extended to all other freeze dried products that are not subjected to virus inactivation procedures in the wet state.

INTRAMUSCULAR IMMUNOGLOBULIN

Immunoglobulins, whether pooled normal human immunoglobulin or specific immunoglobulins prepared by cold ethanol precipitation and administered by the intramuscular route, have an intact safety record with regard to virus transmission covering millions of doses over more than two decades.

Anxiety about the potential of immunoglobulins to transmit HIV has led to a detailed scrutiny of recipients of these products and an examination of the efficacy of the process to inactivate virus. Recommendations by the WHO and investigative procedures carried out by the Office of Biologics of the FDA in the USA maintain the established level of confidence in the safety of fractionated immunoglobulins. These products are therefore not submitted to heat treatment or other virus inactivation procedures which, under current methods, would impair the function of the protein.

THE IMPACT OF AIDS

1. *Raw materials:* all plasma supplied to BPL from NBTS has been tested at source for hepatitis B surface antigen and HIV antibody by Regional Blood Transfusion Centres since 14 October 1985. All tested plasma received at Elstree is securely contained at −40°C for a quarantine storage period of thirteen weeks which permits late reports on donors from the Transfusion Service to reach BPL before implicated plasma donations are entered into fractionation. Identification of a donation (or donations) compromising a plasma pool or batch of intermediate or product would lead to stop on processing, stop on issue or recall in any situation in which recipients of the product would be placed at risk. The donor source of all donations is traceable through to all intermediates and all finished products.

2. *Process changes:* process changes have been instituted as shown above on factor VIII, factor IX, factor VII, factor XI, factor XIII and antithrombin III to permit virus inactivation by heating to take place.

3. *Research and development:* meeting the challenges introduced by HIV infections has required redirection of research and development and a significant diversion of funds into re-formulation of products, changes in processes and methods for introducing virus inactivation without denaturing the protein fractions. The problems posed by HIV in factor VIII were resolved en passant in a more detailed study designed to eliminate the problems of non-A non-B hepatitis. For this reason, BPL was able to respond rapidly and effectively with factor VIII and factor IX products of outstanding safety and efficacy. This was fortuitous, but there is anxiety about the research and development resources currently available and planned for, which will supply the new production facility.

4. *Quality control:* new procedures, equipment and refurbishment of capital facilities are in hand to permit the validation of virus inactivation procedures in all products using model virus including HIV.

UNTESTED PLASMA

The stockpile of fresh frozen plasma and outdated plasma at BPL preceding commissioning of the new factory spanned the date of introduction of HIV antibody screening of all plasma and blood donations by the BTS. Between the 14th October 1985 and April 1986 production continued from plasma untested for HIV. After April 1986, only plasma screened for antibody to HIV has entered fractionation.

As a result, in cold storage there is at present 50 tonnes of untested FFP and 126 tonnes of TEP. An expert committee met at DHSS in January 1987 to advise on the possible use of this material and a direction from DHSS is awaited.

By agreement with DHSS, product derived from untested plasma is presently issued in the following situations:

(i) continuing clinical trial of batches of factor VIII and factor IX used clinically before December 1986;
(ii) 'minor' freeze-dried coagulation factor concentrates (antithrombin III, factor XI, factor XIII, factor VII and thrombin) for which stocks from untested plasma are presently inadequate;
(iii) specific immunoglobulin preparations (e.g. anti-rabies IgG) where stock from tested plasma is not available.

In all cases issues are made to informed clinicians for use under their personal direction.

THE FUTURE

The new production facility at Elstree has the capacity to meet the NHS requirements for blood products and increase pharmaceutical standards in engineering and design to the highest order permitting the process to take place according to the stringent recommendations of good manufacturing practice. The building will be licensed for manufacturing purposes and the products licensed thereafter. The new Blood Products

Laboratory is a national asset both in terms of self-sufficiency and in terms of its intellectual and scientific content and research potential. The Blood Products Laboratory will need growth in both production and R & D areas in that it must continue to manufacture products which match those from industry. The products from BPL must meet the requirements of clinicians and be selected for use in accordance with their practised freedom of prescription.

Biotechnology offers exciting prospects for the development of alternative therapeutic products and it is essential that BPL occupies a central role in any national biotechnology development programme. Recent advances in the manipulation of genetic material, either by recombinant DNA techniques or the creation of cell hybrids producing monoclonal antibodies, has led to the possibility of selectively producing therapeutic protein from micro-organisms, animal cells or cell hybrids in large scale culture systems. The preparation of plasma proteins, notably coagulation factors VIII and IX together with new or trace proteins for which there is no viable plasma equivalent, from clonotypic source materials could yield highly purified products with none of the viral contaminants, e.g. HIV and NANBH, currently associated with human plasma derived products. Pharmaceutical organisations with an established commitment to plasma fractionation are investing heavily in recovering human proteins from such clonotypic source materials. The genes coding for both factors VIII and IX have been isolated and expressed in cultures of mammalian cells. BPL's expertise in the production of clinical products, together with the knowledge and technology inherent to the organisation, should be marshalled to the nation's benefit in ensuring that the development of products derived from biotechnology proceeds to the benefit of the patient, keeping in mind that donated plasma will continue as the source material for many of the BPL's major products.

PRODUCT LIST

FREEZE-DRIED COAGULATION FACTOR CONCENTRATES

Dried Factor VIII Fraction (250 iu/vial)	
Dried Factor IX Fraction (600 iu/vial)	Viral inactivation by heating in the vial for 80°C
Dried Factor VII Fraction (600 u/vial)	
Dried Factor XI Fraction (1000 u/vial)	
Dried Antithrombin III (1000 u/vial)	Viral inactivation by heating in solution for 10h at 60°C.
Dried Factor XIII (500–1000 u/vial)	
Dried Fibrinogen for Isotopic Labelling) (200mg fibrinogen/vial).	Donor accreditation eliminates viral contaminants.

ALBUMIN PRODUCTS

Human Albumin Solution, 4.5 per cent w/v (400ml and 100ml)

Human Albumin Solution, 10 per cent w/v (100ml and 2.5 ml)

Human Albumin Solution, 20% w/v (100ml and 5.0 ml)

(Albumin preparations are subjected to heat treatment for 10h at 60°C in the final container to inactivate viral contaminants.)

IMMUNOGLOBULINS (for intramuscular injection)

Normal Immunoglobulin Injection.

Specific immunoglobulin preparations:–

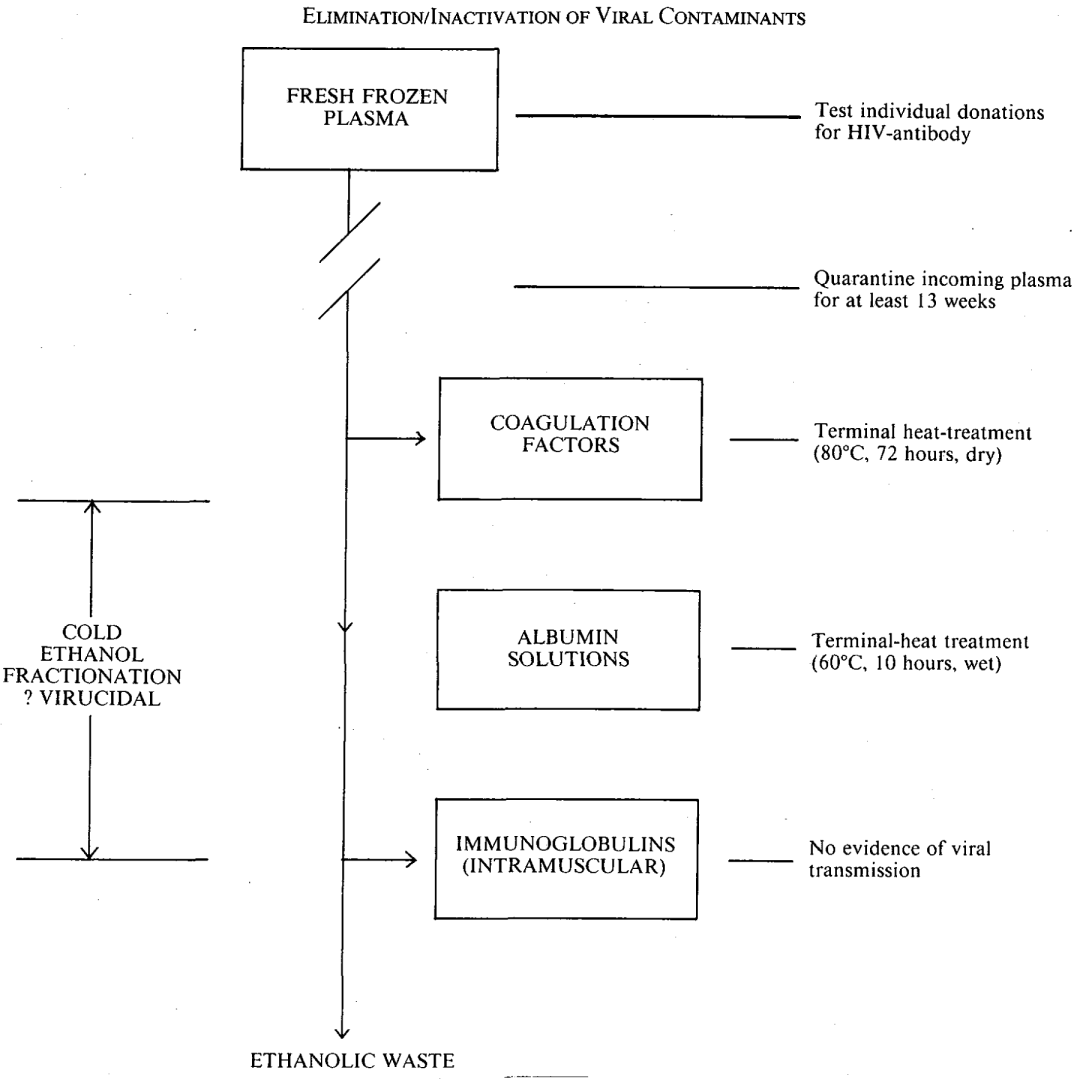
Anti-D (Rho)

Anti-Rabies.

Anti-Varicella-Zoster.

Anti-Mumps.

Anti-Tetanus.



Examination of Witnesses

DR HAROLD GUNSON, Director, National Blood Transfusion Service; DR R S LANE, Director, MR B J CROWLEY, Chief Executive, Central Blood Laboratories Authority, DR T J SNAPE, Head of Quality Assurance and Control and DR J K SMITH, Chief Project Scientist, Blood Products Laboratory; called in and examined.

Chairman

1235. Good afternoon, Dr Gunson. May I welcome you and your colleagues to the Committee this afternoon. We are very grateful to you for agreeing to come and answer some questions and help us with this somewhat complicated inquiry which we are doing. Would you care, first of all, to introduce your colleagues to us?

(Dr Gunson) Let me introduce Dr Richard Lane, who is the Director of the Blood Products Laboratory at Elstree. The remaining witnesses are the staff of Elstree and perhaps Dr Lane can introduce them.

(Dr Lane) I have with me Dr Smith, who is the Chief Product Scientist of our Plasma Fractionation Laboratory at Oxford, Mr Crowley, who is the Chief Executive of the Central Blood Laboratories Authority and Dr Snape, who is the Head of Quality Control and Assurance at the Blood Products Laboratory at Elstree.

1236. Can I put the first question to any of you who cares to reply to it—and perhaps you, Dr Gunson, might wish to reply first—and ask you whether you are happy with the overall level or safety of donated and transfused blood that we have in the country at the present time?

(Dr Gunson) I think that one can never be entirely happy, I think that one has to say that there is a slight risk fron transfusion with respect to AIDS infection or HIV infection; but we have been doing

[Chairman *Contd*]

an assessment since October 1985 and from both our observed results and from calculations that have been made, the chances of a patient receiving a pint of blood that has been collected between the onset of HIV infection in a donor and the appearance of the antibody to HIV, for which we test, is probably less than one in a million. Therefore, with that reservation, I think we would say that the blood supply has the maximum safety that we can obtain.

1237. Would any of your colleagues like to add to that?

(Dr Lane) I would simply say that our position in the infractionation service is that we have the level of assurance that comes from the regional transfusion service since they are the collectors of our plasma; and, on top of that, I think we have a collection of very effective virus inactivation procedures which were applied to the finished product in the case that we have set out in some detail in the presented information to you. So I think that the problem of the donor is felt more at the regional centre than it is now at the fractionation laboratory.

Mr Winterton

1238. Dr Lane, are you planning on instituting blood screening against HIV2?

(Dr Lane) That is not my task. The task of screening the blood rests with the regional transfusion centres.

1239. Dr Gunson?

(Dr Gunson) At this present time, no. We are not planning to do this. The situation with HIV2 infection is being closely monitored with the microbiological services but, at the present time, one has to say that none of the tests that we use will reliably detect HIV2 infection and I do not think that specific tests for this are yet readily available for mass screening of donors.

1240. You say they are not "readily available". Bearing in mind the problems which we are facing, do you not think that if they are available they should be made more readily available?

(Dr Gunson) That could well be an argument, sir, but at the moment they are being used largely in investigative establishments to determine the prevalence of HIV2 infection in various countries.

1241. Do you think, therefore, that we are treating this with the sense of urgency that it deserves?

(Dr Gunson) Yes, I think we are. As far as I am aware, there has been no suggestion that HIV2 infection is very prevalent in this country.*

Chairman

1242. Is it your intention to continue to review the safety of immunoglobulin to ensure that it is as safe as people believe it to be?

(Dr Gunson) Perhaps I may pass that question to my colleague.

(Dr Lane) Immunoglobulin prepared for intramuscular injection is under continuous review, not just in the United Kingdom but worldwide. This is a widely-given product in a very large number of countries and it is monitored. The greater attention has been given to the newer preparations of immunoglobulin that is prepared for intravenous injection. In fact, they have been the subject of considerable scrutiny and now, of course, are processed with additional virus inactivation procedures built into them and the studies that have been done with these particular products are ongoing and they will stay that way.

Mr Lewis

1243. Do you believe that the reliance on self-disqualification by donors from risk groups has been very successful?

(Dr Gunson) Yes, I think that in this country it has been very successful. If I may make one or two statements to qualify that, I mentioned in the report that in one of the London regions where the incidence of AIDS in the population is highest, they have had a questionnaire available to donors who would state whether they wished their blood to be used for research purposes instead of for general transfusion purposes. Less than 1 per cent—in fact, it is 0.5 per cent—of donors attending the clinics in that region have said that they would prefer their blood to be used for research purposes. In those circumstances, the numbers have been small and they have found 2 HIV positive only out of those who had asked for their blood to be used in this way. In many instances, it has been that the donor has been unwarrantably afraid rather than his being in a true risk group.

Mr Yeo

1244. Are you worried about the possibility of false negatives on testing for HIV?

(Dr Gunson) Yes. I think it depends upon what one means by a "false negative". We recognise that there is a gap between HIV infection and the appearance of the antibody where there is a true negative because the antibody is not detectable. As I have said, we think that it is probably less than one in a million donations. True false negatives will occur very rarely because the tests for antibody are, indeed, very highly sensitive. They pick up the antibody extremely well. Since we have been using these, since October 1985, they have become more sensitive, as well. I think that the chances of false negatives are very low.

* *Note by witness*: Additional information to the answers to questions 1239, 1240 and 1241: There is concern within the transfusion service that HIV2 infection, which has been found in West Africa, could spread into the blood donor population in this Country. Whilst we are not proposing yet to introduce *routine* screening for anti-HIV2 (and, indeed, there is no commercial test available for this purpose at present), steps are being taken to examine blood from donors who may be at risk of contracting the virus, i.e. those who have visited particular countries in Africa and, in particular, if they have had sexual relationships with persons living there.

Mr Lewis

1245. Among the people who give their blood —and a moment or two ago you mentioned the questionnaire that was available to them—I take it that those who have said that they would prefer their blood to be used for research purposes may be people who may have some doubts as to how their blood would stand up under test. Have you advised them that they should take an examination of any kind just to prove whether they are positive?

(Dr Gunson) In this region, when a donor states that he wishes to have his or her blood used for research purposes, the donor is contacted and interviewed to find out why this request has been made. In some instances, they were persons in high-risk groups who have come along because of peer pressure—that is, because they could not avoid it, because their workmates were coming to give blood, let us say, or because of things like that.[1]

Chairman

1246. How did you establish that they were in high-risk groups? Did you ask them?

(Dr Gunson) Yes, by interview.

1247. By straightforward questioning?

(Dr Gunson) Yes.

Mr Lewis

1248. But the others who were not in risk groups were just worried that they may have the AIDS virus infection. Have any of them refused to take a test?

(Dr Gunson) Not to my knowledge.

1249. If the infection spreads further through the heterosexual population, will self-disqualification, in your view, still be a sufficient guard?

(Dr Gunson) That is a very difficult question to answer. It may not be. It depends upon whether the spread becomes so great that people would not know that they had the infection. But at the moment, I must say, there is no evidence that such a degree of spread into the heterosexual population is taking place. Almost all of those donors that we have found antibody positive are either young homosexual or bisexual men or intravenous drug addicts. You can classify all but six out of the 70 into recognised risk groups. The six that cannot be classified deny that they are in a risk group.

1250. You may not have this figure but what is the percentage of those in the homosexual group who have offered blood together with those who use the syringe, the drug addict, who have offered blood. Have you any figures on that?

(Dr Gunson) The figures to date are that 70 donors have been confirmed as anti HIV positive. I think that the number of homosexual and bisexual men in that group is something like 20 to 25 and that there are about 12 to 15 intravenous drug addicts[2]. There is a different distribution throughout the country. Most of the donors who have been intravenous drug addicts have been found in Scotland rather than in England. That is the commonest cause for the finding of anti HIV positive among the Scottish blood donors.

Mr Yeo

1251. Are your self-disqualification questionnaires available in languages other than English?

(Dr Gunson) No. At the present moment, I think they are not.

1252. Do you have any plans in that respect?

(Dr Gunson) This has been discussed but I am not sure just what the plans may be at the moment. One has to say that the great majority of blood donors in this country speak English.

1253. Can the blood transfusion service cope with the wider ramifications of screening blood—such as the counselling of those who are found to be anti HIV positive?

(Dr Gunson) Yes. We have undertaken counselling within the allocated resources for the transfusion service. When we were providing estimates for the cost, we were able to determine the cost of the testing because that was a definitive factor but, until we knew the numbers that we would have to counsel, it was not possible to provide any estimates of this. In fact, the numbers of donors found to be anti HIV positive have been so small that it has been possible to contain this within the medical staffing structure and our current estimates.

1254. Do you have any evidence that people are using the blood transfusion service as a means of screening themselves?

(Dr Gunson) This may well be the case. It is something which we could not possibly rule out. There is possibly one slight degree of evidence that this may happen to some degree in that the percentage of new donors—and that is defined as those giving for the first time—that are anti HIV positive has been consistently higher than for old donors. Of course, the old-donor figure is difficult to assess because the donors give multiple donations and one would expect it to be a lower frequency, anyway. But, right from the beginning, that has been a factor and there is a possibility that some of the new donors are coming to find out their anti HIV status.

Mr Winterton

1255. While you referred to this matter, Dr Gunson, a little earlier in the evidence that you have given to us, could you perhaps describe in greater

Notes by witness:

[1] Comments on Question 1245: The questionnaire is only being used at one London Regional Transfusion Centre, where there is a higher than average incidence of AIDS infection within the population of that Region, as I explained in my answer to question 1243. Perhaps I should have stressed this point in answer to question 1245 since it has not yet been considered necessary to have a questionnaire available for donors in other Regions, although this is being kept under close review.

[2] The exact figures for homosexual and bisexual men is 30 and for intravenous drug addicts, 15.

detail how you and your colleagues are coping with the problem of blood donated during what I think is described as the "window period" between infection and seroconversion?

(Dr Gunson) Well, of course, there is nothing that we can do to affect this, because this is the limitation of the testing that is available at the pesent time. We can only test for antibody. The tests have a given sensitivity so that you can only detect a particular minimum quantity of antibody; and current evidence suggests that there may be a period of a few weeks between the acquisition of infection and the appearance of the antibody where we are unable to provide evidence of HIV infection. The only way that we can combat this is to make every effort to ask those persons in high-risk groups not to donate blood. That has to be an important policy running along with the antibody testing.

1256. You do not believe that we should institute a system whereby people that are donating blood to the blood transfusion service come one month and then come back, perhaps, six weeks later to give a further quantity of blood which, again, will be subject to test; so that you could be quite sure in yourself that you are not taking blood which is in any way infected?

(Dr Gunson) No, sir, I do not think that that can be done. Logistically, that would be extraordinarily difficult. I think that we would lose a lot of donors. But, you see, there is no guarantee if they come for the second sample after six weeks that you should not regard them as having been infected during that six-week period.

Chairman

1257. And what are your thoughts on this, Dr Lane?

(Dr Lane) We start from a basic assumption that plasma contains live virus of some sort, perhaps quite a large number of different viruses. Our main concern over the years has been with the viruses as yet unidentified which cause non-A non-B hepatitis. Therefore, we know that a substantial amount of plasma that comes into the fractionation centre contains these viruses. Therefore, we make the assumption that there would be HIV in the plasma at some time and, therefore, the whole process is directed at the containment of the risk of spread of that virus between batches of material, for example. Then, at the end, we have a process which is aimed at inactivating all viruses. We were, in fact, in the process of developing products which would inactivate the non-A non-B hepatitis viruses when HIV became a problem. I think that it has been dealt with as part of that overall programme. So that we have dry-heat treatment for our coagulation products and the standard pasteurisation for albumin which, I think, has years of assurance behind it.

Sir David Price

1258. I think that leads very logically to the next question that I wish to ask. What do you do with donated blood or blood products when you are unsure of its safety?

(Dr Lane) With any blood product, if we are unsure of its safety, it is not actually released. It is not released, it is not issued, for use. The only way in which we could say that we are unsure of a blood product is because it does not meet the quality control parameters that are set down for each and every product that we have. If a product does not meet those parameters or, in fact, if there is an additional risk factor which falls outside—as, for example, the contamination of a pool by a donor where we have late information about the status of that donor—that pool of plasma is rejected and the product is rejected.

1259. But what do you do with it when you reject it? How do you dispose of it?

(Dr Lane) You can autoclave it——

Mr Lewis

1260. If I may follow on Sir David's question, since the spread of the virus has come about and since you started screening, what would you say has been the percentage of your blood stock that you have had to put in the incinerator?

(Dr Lane) At this particular time, we have a volume of plasma that has been collected before testing was instituted by the regional service. That plasma is at the moment under curfew, it is not for process. The Department of Health and Social Services is discussing at this stage what we should do with that material. As far as the other products are concerned, I think that Dr Snape would be able to say how many batches of material that we have withheld as a result of late notification of AIDS during the last two years.

(Dr Snape) The vast majority of instances lead to plasma being rejected before it is pooled for fractination and before fractionation is complete. That does not have a significant impact on our product. We have rejected—and I do not have precise figures—between four and six batches in the last two years for causes in some instances directly associated with AIDS and, in other instances, associated with known individuals likely to transmit non-A non-B hepatitis.

Sir David Price

1261. So they may have been picked up at regional level before reaching you?

(Dr Snape) The problem would always be identified at regional level. The action to exclude the donation or the product would be either at regional level—in which case we would know nothing about it—or would be identified and subsequently excluded from our own stocks.

(Dr Lane) I think that Members would like to know that we have got a stockpile of fresh plasma being developed now for use in the new plant which represents a three-months period of effective quarantine. That three-months period has developed around historical problems from hepatitis B, in fact, but there is also an economic element about it because it represents about seven million pounds worth of plasma. One has to draw a line somewhere between the effective size of the quarantine pool and

[Sir David Price *Contd*]
batches that you may lose because of late notification and, as you have already heard, the number that we have lost is really very small.

Chairman

1262. You said seven millions?
(Dr Lane) Yes.

1263. I am not sure whether you are talking about cost or weight.
(Dr Lane) It is cost.

1264. Cost, is it? My Goodness! How much does that £7 million represent?
(Dr Lane) At the present time, it is much greater than that. Our normal quarantine pool would represent perhaps four months' supply and we process about £22 million worth of plasma a year.

Mr Galley

1265. Dr Gunson, your Paper refers to increasing requests for autologous transfusion which, as I understand it, refers to people donating their own blood in advance of need who may be transfused with that blood in due course. That proposal has received some support, in particular, in a recent article in the BMJ. You seem to be rather cool towards it. Can you eloabrate on your reasons for not being too enthusiastic?
(Dr Gunson) I think that there is no doubt that some patients will be in a position to donate their own blood during the period in which we can store it, which is 35 days prior to an operation. But I think that one has to recognise that this will apply only to a relatively small percentage of patients undergoing planned surgery. This is because many patients undergoing planned surgery are very ill and would not be in physical condition to donate their blood. Many are too anaemic to be able to donate their blood. Others are of an age where taking off three or four units during a month period would be medically inadvisable. And there is, of course, a large number of children from whom it would be extremely difficult to obtain adequate supplies of blood before planned surgery. Therefore, while it may be valuable in certain instances, my estimate—and I accept that this is a personal view—is that it is so in probably no greater than 5 per cent of the total planned surgery that is carried on in the hospitals throughout the country.

Chairman

1266. Do some relatives give blood for their relatives who are likely to undergo surgery—parents of children, for example?
(Dr Gunson) That, again, we have actively discouraged because relatives and friends who were to be asked that they should donate for a patient would have to undergo all the tests that we carry out for our normal donor panel. Indeed, there is no guarantee that the blood from what we call directed donations from friends and relatives is any safer than the blood that we are producing from our voluntary donors. Indeed, there may be instances where relatives would not be able to declare that they were in a risk category because of the emotive involvement with the patient. So that we find that directed donations is not a thing to be advised. I think that that is different from the autologous donation.

Sir David Price

1267. You have said that 35 days is the limit?
(Dr Gunson) Yes.

1268. But, surely, blood can be kept frozen and still be useful beyond 35 days.
(Dr Gunson) Yes. It can be kept frozen for considerable periods.

1269. For how long? Could you be more specific?
(Dr Gunson) I think that you could keep blood frozen for up to five years and possibly longer. But the cost of doing this is extremely high. Also, it can be available only at certain centres in the country. I do not think that this could be a facility that could be made very widely available throughout the hospital service. Therefore, the availability of frozen blood is difficult. It also takes something like one and a half to two hours to bring up the frozen blood to a useable state from it being frozen. This means that while that may be satisfactory for a planned operation, it would be of little value for emergency purposes, which really would be the particular value if you were going to freeze it.

Mr Galley

1270. But some individuals regard it as of value. It may calm fears in certain instances. Why not make the facility available? It may be that you will have to say that the cost is such that you will have to make a small charge for this facility, a charge which may, indeed, cover the costs of the storage.
(Dr Gunson) That may be so. We have worked on the premise at the moment that frozen blood banks, as such, in our view would not be very practical but the question of persons donating within the 35-day period could well be practical for some persons. We are, in fact, trying to devise guidelines for such procedures at the present time.

1271. But is it not practical simply because of the cost implications and the delay in an emergency? Are they not two critical factors?
(Dr Gunson) There is cost, there is the logistics of setting up such a frozen-blood bank on a large scale. We have four frozen-blood banks that store cells in the frozen state in the country at the moment. But these are largely for cells of a very rare type to which patients with very rare blood groups can donate. To do this on a very large scale for the general population would provide serious logistic difficulties.

1272. But if you discourage autologous transfusion or directed donations, is there not a chance that there would be an increase in the number of pirate blood banks that will start to operate and that people will go to them?
(Dr Gunson) Not necessarily. I think that the discouragement of autologus transfusions would be purely on clinical grounds. As I have said, we are

[Mr Galley *Contd*]
trying establish guidelines for autologous transfusions at the present time. Where this can be done, it may well be of reassurance to the patient and a benefit to the patient. But it must be recognised that there will be clinical conditions where this is not possible.

Chairman

1273. On the other hand, there must be certain clinical conditions where it will be of advantage?
(Dr Gunson) Yes.

1274. Should you not be catering for those conditions?
(Dr Gunson) As I say, we are looking into the question of autologous transfusions at the present time because there has been considerable requests throughout all the centres and the hospitals for this. One has to counter this, too, with the fact that, of course, those patients who cannot give their own blood must be reassured that the blood transfusion service really has a very safe product, indeed. There are many patients going for surgery who would not be able to give their own blood even in the frozen state and have it kept for them. I think that it would be unfortunate if those patients felt that they were at major risk, because I do not think that they are at major risk.

Mr Winterton

1275. You have introduced another line of argument in this. First of all, you seemed to say that there were clinical objections to members of one-family giving blood to another member of the family. Yet you have just said that perhaps the reservation is that it might reflect badly on the rest of the blood transfusion service that you are not actually giving a really reliable product. To me, it seems that you are arguing against yourself. I should have felt that if a member of the family—and particularly a blood relative—can give blood to another relative, as in the case of a human transplant, that is much better than getting a product from elsewhere. So why are you not actually making greater progress in looking into this matter, as my colleague has implied?
(Dr Gunson) There are two matters which have become rather mixed up. One is autologous transfusion, where a person gives blood to use for themselves. That, I say, will be applicable in certain instances. There may be clinical grounds on which it is impossible to obtain the blood from a person who is going to have a particular operation. The second matter is what is known as directed transfusions where friends and/or relatives give blood for a patient. In these instances——

1276. You say that you have resisted them.
(Dr Gunson) We have resisted these because our argument is that such blood has no chance of being any safer than the blood that we are using through our general donor population.
Mr Winterton: But you would test it, would you not? And if it were useful, you could use it. The point I am making is that I think it would give a lot of reassurance to people who might not be looking forward to an operation of which a blood transfusion was part to know that, in the course of that operation, they would be getting blood from a member of their family. Is it not worth operating that sort of a system for people who want that sort of service?—as, again, my colleague said in his questions to you a moment or so ago.
Mr Galley: Yes. Why rule this out?

Mr Winterton

1277. Precisely! Why rule it out?
(Dr Gunson) Our reasons for ruling it out at the present time, as I have said, are that we would not consider such blood to be any safer than the general blood that is collected by the transfusion service.
Mr Winterton: You have just said that there was a chance of one in a million. That, I think, is what you have said. I would say to you that if I got blood from my son, from either of my sons or from my daughter or my wife, there would not be, in my view, even one chance in a million that it was infected. To me, it would be an immense reassurance to know that I had got blood from a member of my family.

Mr Lewis

1278. Is it of the same category?
(Dr Gunson) Of course, in all this one has to temper it with the fact that people's blood groups are different and family members and friends may not be of the same blood group, of course.

Mr Galley

1279. But you would test that before, would you not?
(Dr Gunson) Yes. That would be tested before.

1280. May I clear up a point on autologous transfusions? Are you saying that it would be clinically unnecessary and that it would be just for reassurance; or are there occasions when it might be clinically necessary and desirable?
(Dr Gunson) If you accept that there is one in a million chance of getting HIV infection from our donor blood, if a person gives blood for himself or herself then they do not contract any infection that they have not already got in their own body. Therefore, you can say that that is entirely safe from the transmission-of-infection point of view. It has problems from other points of view. The first is that you have to make absolutely certain that the patient gets back his or her own blood. And, when you have a lot of such patients, making sure that the blood is given to the right patient is a matter that has to be addressed very seriously. But there are clinical conditions which would prevent a patient from donating his or her own blood. Also, of course, there is no guarantee, once the operation has started, that more blood is required than the patient could possibly donate. Therefore, the patient would have to go on to the blood transfusion service product, in any case. There are problems with autologous transfusion but what I am saying is that it may well be possible in a percentage of patients to employ autologous transfusions. The transfusion service at

[Mr Galley *Contd*]

the moment is actively looking into this and producing some recommendations and guidelines for the hospital service where it will have to be carried out.

Chairman

1281. Perhaps I could ask Mr Crowley if he could give his views as to whether it is possible for the United Kingdom to become self-sufficient in blood and blood products.

(Mr Crowley) I think that it is possible. Indeed, the whole thrust of this—may I say, surprisingly well-judged—investment into the new facility at Elstree is based on the assumption not only that we can achieve a large measure of self-sufficiency but also that we will generate some surplus which will provide us with a measure of income for the facility there which, hopefully, we may then direct into further research and development further to improve our processes. That is definitely a possibility. The one question that one would have is whether we can be assured of a sufficient supply of plasma to feed this "monster". At the moment, that remains a slight unknown and I think that possibly both Dr Lane and Dr Gunson could address that with more credibility than I could.

1282. Thank you. Dr Lane, perhaps you could give us your view.

(Dr Lane) At the present time, the transfusion service is responding well to the targets that have been set for plasma collection. If the trend continues then there will be sufficient plasma to meet the targets for production in the new building.

Mr Winterton

1283. Who sets them?

(Dr Lane) We set them. The point, of course, is that plasma collection is dependent for the most part on plasma derived from whole blood. There are other ways of getting plasma, of which automated plasmapheresis is one that is preferred in the United States by the United States industry. This is a method of plasma collection independent of the transfusion service and therefore independent of donor-related problems. I think that one cannot ignore the effect of AIDS on donor-related problems. Therefore, we may have to examine the trend in donation to determine whether the accentuation in the future should rest with our existing main thrust from whole blood or the provision from plasmapheresis. At the end of the day, I think that the problem is mainly resolved by finding sufficient money to do it. As long as there is sufficient money to do it, I have very little doubt at all that the transfusion service will be able to to do it. I think that the interesting thing about plasmapheresis is that, because one can obtain raw materials in the form of plasma from a plasmapheresis donor a much larger number of times a year than one can obtain whole blood, one's record—if you like—of that individual becomes more precise, greater in depth and, therefore, more assured. I think that that is something that we need to bear in mind for the future. That is not to say that I am dissatisfied at the present time with the quality of the plasma that I get; because I certainly am not. But I do believe that it can happen and I think it will require a measure of awareness of trends and it will require cash.

1284. Do any of you see any problem about resources for this work in the future?

(Dr Lane) At the present time, the resource allocations for making the Blood Products Laboratory work are being provided in sufficient amounts for us to be able to carry out our production operations, commission the new building and hopefully get the work up in the shortest possible time.

(Mr Crowley) I mentioned the very substantial investment that has been made in this new plant and which we are currently commissioning. I hope that the Members of the Committee, when they have time, will pay a visit to this facility. It is a really superb facility.

1285. Thank you for the invitation. We shall see what we can do.

(Mr Crowley) I should like to emphasise to the Committee that this should be viewed much more than simply a production plant. It has to be supported by adequate research and development. We have seen a graphic example of that in the way work to resolve the hepatitis problem proved to be very relevant, indeed, in resolving the AIDS problem. The thrust of this sort of work must continue so that we keep ourselves fully in advance of the technology that is available.

Mr Lewis

1286. Am I correct in assuming that the spread of this disease has meant, as far as your department is concerned, a heavier workload in terms of screening and whatever and that therefore you have had to employ extra staff to help you cope with it?

(Dr Gunson) Yes. We have employed extra staff in the regional transfusion centres to perform the screening tests on the blood donations. But this has meant no more than—I would say—a maximum of two, possibly three, technical staff in those centres, because we combine the work of screening for the anti-HIV with the screening for hepatitis. It is usually done in the same department and the two tests have an overlapping technology. But there has been some additional staff on that score.

Chairman

1287. I think that that concludes the questions that we wanted to put to you. Thank you very much indeed for your help. We are most grateful.

(Dr Gunson) Thank you.

1288. And we shall consider your kind invitation.

(Mr Crowley) Thank you.

Memorandum Submitted by Professor Ian Kennedy*

AIDS: THE ETHICAL AND LEGAL ISSUES

ETHICAL ISSUES

A. *FACTS about HIV infection and AIDS*

No discussion of ethics (or law) can be conducted without the best available information.

(a) Numbers (present and projected) of HIV infected persons and AIDS sufferers.

(b) Relationship between antibody positive status and AIDS.

(c) Risk categories.

(d) Definition of AIDS (i.e. what is regarded as AIDS).

(e) Mortality among AIDS sufferers.

(f) Facilities for caring for AIDS sufferers.

(g) Risks to which carers (doctors, nurses) and others, e.g. technicians, emergency services (police, fire) are exposed.

(h) Costs (human and material; present and projected) of:

(i) caring for AIDS sufferers
(ii) testing for HIV
(iii) counselling and informing patients and public
(iv) educating public.

B. *General themes*

In addition to commonly accepted principles of medical ethics (avoiding harm seeking to do good, respecting persons, doing justice), there are certain themes which run through any discussion of ethical issues arising from AIDS. These are:

Individual (rights and duties) vs. Society (rights and duties)

Caring vs. Judging

Advising and Counselling vs. Adopting any particular moral posture.

C. *Particular Issues*

1. *Resources:* (human and material)

There are two main questions

(a) What ethical principle(s) can serve to determine what proportion of limited health care resources should be allocated?

(b) Using these principles, what resources should be allocated in responding to HIV infection and AIDS now and in the foreseeable future.

Costs arise from

(a) Care of AIDS sufferers in (i) hospital
(ii) hospice
(iii) home-community.

To what extent do decisions, e.g. in favour of (iii) and the "partnership in care" scheme, reflect ethically valid allocation of resources as opposed to opting for the cheapest response?

(b) HIV testing

To what extent should resources be diverted by the NHS to meet existing demands for technicians, laboratories, counsellors, whether in STD clinics or elsewhere, and for the training of additional personnel?

(c) Demand for information

To what extend should resources be diverted or allocated by the State to provide information by telephone or otherwise?

* Professor Kennedy's paper was originally prepared for a seminar at King's College London, February 1987.

A further question arises as to the extent to which costs should be borne by the State or by Voluntary Agencies, with or without support.

Finally, to what extent should such discussion take account of the resources allocated to and needed for such illnesses as, cervical cancer, cancer of the breast, cystic fibrosis or multiple sclerosis?

2. *Screening/testing for HIV*

In any consideration of screening, the following interrelated questions should be borne in mind:

What is the purpose of the screening

Who should be screened?

Should screening be voluntary or compulsory?

Is the cost justified?

(a) Screening for prevalence—the need for epidemiological data is clear. Can this justify compulsory screening, or screening blood submitted for testing for other purposes (e.g. a blood test for mononucleosis)? Is the latter valid if the donor of the blood sample cannot be identified?

Counter arguments to compulsory screening relate to invasion of privacy, possible leaking of information (with consequent ill-effect for individuals identified as being HIV infected), and the danger of the process being counter-productive in that people at risk would avoid the test, so driving the illness underground and putting society at greater risk.

(b) Voluntary screening for, e.g.

(i) employment
(ii) armed forces
(iii) insurance
(iv) pregnancy
(v) advice from FPA
(vi) marriage licence.

As for (i) and (ii), is the screening really voluntary and what justification exists for it, particularly as AIDS is ordinarily associated with sexual intercourse? Also, is there a moral obligation to employ the disabled?

As for (iii), insurance is a matter of private arrangement, but to what extent is such discrimination legitimate?

As for (iv), this may be deemed justifiable but it raises, as does all pre-natal screening, the issue of abortion.

As for (v), to what extent can it be justified to impose a condition that a person seeking advice on family planning be screened?

As for (vi), there may be a difference between providing those contemplating marriage with information and making submission to screening a condition for acquiring a marriage licence. What purpose would be served?

(c) Compulsory screening of certain groups, e.g,:

prostitutes
members of armed forces
employees in certain jobs
those in prison.

Apart from the issue of civil liberties, further questions arise as to the value of such screening, what would be done if the test were positive and whether any such measures would be enforceable by, e.g., the police.

3. *Confidentiality*

The issue here is whether it may be justified to tell others, without the consent of the patient, of the patient's condition.

If confidentiality is not an absolute obligation, it may be that breach of confidence may be justified only where there is *real* risk of harm to others. The issue arises as regards the following three categories of person:

(a) those involved in the medical management of the patient

(b) those who may be at risk when caring for a patient, e.g. technician, porter

(c) others, e.g., dentists, parents, sexual partner or contact, employer, police.

4. *Research*

(a) In the treatment of AIDS sufferers, the question may arise whether the normal rules governing therapeutic research need apply, e.g. controlled trials, animal research, etc. A counter argument may be that without observing such rules, any results produced may be bad science and bad science is unethical.

(b) Can it be justified to give highly toxic drugs to volunteers who agree in desperation? The response may be that the ordinary rules of medical ethics concerning consent would appear to apply.

(c) What are the responsibilities of scientists and the media concerning reports of alleged breakthroughs? Arguably scientific results should be reported after peer review and not in press conferences so as to avoid misinformation and false optimism among the sick.

5. *Health Care Providers and others*

The issue here is the obligations which health care providers and others may properly be expected to undertake and the risks they ought to accept.

The key must be information (on which see 6. Health Education).

The risks would appear to be within the range of risks ordinarily accepted, such that a doctor or nurse ought ordinarily to care for a patient subject to protection when necessary. It would follow that a GP should not strike off a patient from his list nor should a nurse consent to care for a patient only if dressed like an astronaut. For others, such as the police or fire services, the analysis may be the same. One proposal is that an identifying disc be worn to alert such persons. Besides being impractical, this may be said to be an unwarranted stigma.

It may be important to notice the difference between *risk perception* and the real risks, but this, as has been said, is a matter of health education.

6. *Health Education*

The overall question must be the extent to which the benefits in the form of increased knowledge and awareness outweigh any harms done, such as the dehumanising impact of certain information, the dissemination of information which is partial or premature, or the apparent endorsement or legitimation of certain conduct.

(a) Facts—In addition to the factual information referred to earlier, other material may well be called for before a sensible and defensible policy of health education can be launched, together with the necessary funds. Research may be needed on, e.g.

(i) the sexual behaviour of homosexuals
(ii) what intravenous drug users actually do: why, e.g. they share needles, whether it is for social reasons rather than scarcity.

(b) Policy—Questions arise as to the propriety and efficacy of certain measures which have been adopted or proposed.

(i) Does health education aimed at, e.g. "safe sex" and the sharing of needles concentrate too much on the capacity of individuals to make rational assessments at times when they are least likely to do so?
(ii) Does the "safe sex" policy induce a false sense of security by suggesting tht a reduction in the number of partners is sufficient? If the disease is endemic *fewer* partners may not be good enough.
(iii) Traditional public health policy would concentrate on the identification of carriers and contacts. So far this has not been the policy adopted, for at least three arguments: confidentiality, the fact that AIDS is not a notifiable disease and the impact on the sufferer if informed may be psychologically harmful. Are these arguments sound, or are the counter arguments more sound, particularly that of driving sufferers underground?

More specifically

(i) Should health education policy concentrate on advocating one sexual partner for life?
(ii) Should education be targeted at risk groups or at the population at large, given the incidence of infection and the costs involved?

(iii) Should condoms be made available freely
1. for all, through GPs who at present cannot supply them, unlike Family Planning Clinics
2. for prostitutes
3. in schools
in prisons [? should prisoners with AIDS be isolated].

(iv) Should clean needles be issued, or an exchange system for needles set up or the Dutch system be put into operation.

7. *Moral and Religious Positions*

What weight, if any, should be given to condemnations of homosexual conduct, promiscuity (however defined), the notion of "safer sex"?

How is the tension between caring and condemning to be resolved by those who regard AIDS as (in large measure) a consequence of sin or wrongdoing?

LEGAL ISSUES:

Many of the ethical issues also involve questions of law, either in terms of existing law or of proposals for legislation.

Furthermore, as was the case with ethics, the legal issues reflect a tension between concern for an individual's civil liberties and for the needs of the public. In resolving problems which involve this tension it must be borne in mind that, while English law concerns itself more with remedies than with rights, the European Convention on Human Rights establishes certain rights enjoyed by every individual and could well be called into play as legal issues, particularly involving forms of discrimination, arise.

Many of the legal issues identified have yet to arise either because no legal decision has yet been reached by a court or because proposals for legislation or regulation have not yet been acted upon. It is important, however, both to seek to predict how a court may decide a particular question so as to advise interested parties and to examine proposed laws in the light of prevailing views of fairness, of civil liberties and of human rights.

1. *Civil liberties and discrimination*

(a) Public Health (Infectious Diseases) Regulations 1985:

(i) What is the precise scope of these Regulations?
(ii) What are the powers available under the Regulations, e.g. is there a power of obligation to treat?
(iii) Are the Regulations necessary or warranted?
(iv) Are the Regulations capable of being enforced or policed?
(v) Are the Regulations counter productive, in terms of causing sufferers to avoid help and thereby exposing society to greater risk?

(b) Should AIDS or HIV positive status be notifiable, with the availability of the consequent powers under Public Health (Control of Disease) Act 1984.

Would such information if reported be secure from leaks? What if any impact would the Data Protection Act 1984 have?

Is such information warranted? Would reporting and the consquent potential restrictions which could be placed on individuals be counterproductive?

What is the experience in other countries in which AIDS is a notifiable disease?

(c) Is a doctor entitled in law (or ethically justified) in using the 1985 Regulations as a threat if a patient appears unwilling to change behaviour which puts others at risk?

(d) Are the following in conformity with English law, the European Convention on Human Rights or otherwise justifiable:

(i) compulsory testing for HIV (see *ante* for some counter arguments)
(ii) compulsory detention or quarantine of AIDS sufferers or HIV infected persons
(iii) travel restrictions on HIV infected persons or AIDS sufferers
(iv) identity tags, discs or cards for HIV infected persons or AIDS sufferers
(v) compulsory testing for HIV as a condition for obtaining a marriage licence

(vi) compulsory testing for HIV of pregnant women
(vii) compulsory testing for HIV of persons in prison
(viii) compulsory testing for HIV of members of the armed forces and those seeking to join
(ix) compulsory testing for HIV of employees in certain forms of employment and of persons seeking employment
(x) the requirement of submission to a test for HIV as a condition of obtaining health or life insurance
(xi) compulsory testing of prostitutes.

Are any of the above practical possibilities in any event? If so, would the results obtained be of any value?

2. *Confidentiality*

In any legal action brought by someone who alleges breach of confidence, if that information concerning HIV infection or AIDS was transmitted to another *without consent*, the person transmitting the information may plead the defence that he acted in the public interest. How far does this defence extend?

Does it apply, for example, in the following situations

(a) communication to others who may have to treat a person with AIDS

(b) communication to others where there is a threat to public health or to health and safety at work

(c) communication to environmental health department with a view to controlling the spread of infection to others

(d) communication to others, e.g. employers, contacts or partners, parents, police, social services, dentists.

Do the provisions of the N.H.S. (Venereal Diseases) Regulations 1974 apply in the case of HIV infection or AIDS?

Is contact tracing, whether of homosexual or heterosexual contacts, legally defensible (or practically justified)?

3. *Legal liability of doctor and other carers*

Many of the issues raised here at the obverse of those raised under the heading of confidentiality.

Does the doctor face legal liability in, e.g. the following circumstances

(a) the doctor fails to warn other patients, e.g. spouse, who may be expected to have sexual intercourse with a patient who is discovered to be HIV infected, and the other patient suffers harm. Would an action in negligence lie against the doctor?

(b) the doctor fails to warn others, ranging from other doctors to other carers, to health authority, to social service department, to employer and other foreseeable contacts and harm ensues to such a foreseeable contact. Is the doctor liable in negligence?

(c) the doctor fails to explain "safe sex" to a patient whom he knows to be at risk, and he subsequently becomes infected. Is the doctor liable in negligence?

(d) the doctor in occupational medicine carries out instructions from an employer to identify and exclude from those applying for employment those suspected of being homosexual and therefore at risk, such that it may be a poor investment to employ and train him. Is the doctor in breach of any law? If not, does the law need amendment?

4. *Criminal or civil liability of HIV infected person*

Does a person who knows he is infected with HIV and knowingly exposes another to the risk of infection commit any crime or civil wrong, e.g. a crime under s.20 or s.23. Offences Against the Person Act, 1861, or the tort of battery or negligence.

5. *Civil liability of providers of blood and blood products*

Should a person become or have become infected as a consequence of a transfusion of blood or blood products, despite attempts to ensure that this will not occur, at least two questions may arise

(a) Is the supplier of blood liable in tort for harm done. In this context the development of product liability and the defence of "State of the Art" may be relevant.

(b) Can the person harmed obtain the identity of the donor of the infected blood so as to bring an action against the donor, assuming it were worthwhile and the donor knew or ought to have known he was infected?

Examination of Witness

PROFESSOR IAN KENNEDY, Centre of Medical Law and Ethics, King's College, London; called in and examined.

Chairman

1289. Thank you very much, Professor Kennedy, for agreeing to come and help us.

(Prof Kennedy) I am happy to be here.

1290. May I start by asking you if patients have an absolute and constant right of confidentiality in respect of AIDS and all its accompanying problems?

(Prof Kennedy) I think that it would be wrong to think in our society that there is an absolute right to confidentiality. I do not think that we have ever recognised it. In ordinary medical practice, we have recognised that there are some good reasons why, in some circumstances, we would want to tell someone else. Indeed, the GMC, in its Blue Book of guidance to doctors, recognises a number of exceptions which range largely in terms of the public interest in confiding certain things in other people. So that, if that is the case generally, it strikes me that it would equally apply to AIDS except that, in the context of AIDS, because of the stigma which has been attached to having this illness and because of the contingent consequences which might flow, one would argue that very, very great caution be exercised—even more than perhaps there is at present—before such information was imparted to anyone else. For my own part, I think that it is only proper to tell people about a person who is HIV infected or has AIDS in circumstances where there is any real risk that that person has been put at risk or, alternatively, where there may be some public interest in terms of protection——

Mr Winterton

1291. Who is going to be the judge of that risk?

(Prof Kennedy) I think that in all matters having to do with confidence, the person who is the holder of the confidence is the only person who can judge that. Otherwise, we cannot be talking about telling someone else. If you have my secret only you can judge whether someone ought to know.

1292. In the case of a plague disease like AIDS, do you think that that is appropriate?

(Prof Kennedy) I think that in all matters where we are talking about the relationship between doctors and patients, as we are, perhaps, in the context of your question, one ought to begin with the notion of retaining the ordinary aspects of a doctor/patient relationship to which the keys are trust, voluntariness, confidence. If we abandon those we, as it were, ask our doctors to behave in a way in which ordinarily they do not behave and we ask patients to perceive their doctors in a way in which they have not ordinarily done so—with certain consequential possible disadvantages. So that I would say that even in this context it is right to begin from that position and then look for whether there might be justifiable exceptions. I mentioned one, such as those who are otherwise involved in the care of patients and who might be put at risk or, alternatively, when the local health authority or its officers might need to know for the purposes of prevention of the spread in certain circumstances.

1293. You do not think there is any correlation between AIDS and other diseases of which you have to notify the authorities?

(Prof Kennedy) There may be similarities in some respects in so far as it may be categorised as an infectious disease. If the question is whether it should be categorised as a notifiable disease, I think that there may be arguments which go both ways. But I think that, on balance, the argument would be against having it categorised as a notifiable disease —not really on ethical grounds but rather on grounds of whether that will produce the result that one wants. If it is the case, and there is some argument elsewhere that categorising it as a notifiable disease will, in fact, deter people from showing up for care or having tests or whatever because of the consequential stigma associated with the possibility of job loss or the possibility of losing accommodation, it may simply be counterproductive to include it in that.

Chairman

1294. How does that apply to pregnant women? —because the Department have announced a new policy on that. Is a pregnant woman to be told?

(Prof Kennedy) I understand that the Department is considering the circumstance of pregnant women. In my view, it would be entirely appropriate to ask pregnant women whether they wished to be tested. I

[Chairman *Contd*]

am sure that many of them would wish to be tested. This is a slightly different question and does not really raise the issue of confidence so much as the issue of whether one ought to find out certain things. In that case, I am quite persuaded that pregnant women ought to be asked. I am not persuaded that one ought to go and do it without asking—which perhaps we may come to later.

1295. I think that the idea was that they would be asked: but then there are implications if she is found to be positive?

(Prof Kennedy) There are always implications in any antenatal screening that one contemplates abortion as a consequence. I think that about 10 per cent of all women who may be pregnant at any given time would not be in favour of abortion for whatever reason. In those circumstances, one is presented with the same problem that one has in any screening in an antenatal context.

Sir David Price

1296. May we go back to your classical statement of confidentiality? There is another aspect on which you touched only indirectly. That is, the need to know, clinically and socially. It seems to me that this is something in which even the medical profession in relation to AIDS are very uncertain. Following the Chairman's question, it applies also to telling partners. If a husband is found to have AIDS, one can argue very strongly on purely clinical grounds that if he will not tell his wife, his wife ought to be told.

(Prof Kennedy) Sir David, I agree that there are various classes of person. The first class must be those who are immediately involved in the care of that patient, whether they be doctors, nurses or whatever. I think that whenever they are involved with sharp instruments in caring for the patient, they ought to be aware. Largely, they will be so, in so far as they will be looking at the notes and knowing what patient they are nursing. When one comes to other categories of people, whether they be dentists, employers, the police and so on, I think that in nominating the spouse you probably have the strongest candidate for someone who ought to be told ordinarily, particularly if that spouse happens to be your patient also. It seems to me to be a clear case where your duty may be to be concerned for your patient's health and the possible risk that she is at rather than respecting confidence. I would think that it would be a case where one could properly break confidence.

1297. This is not a theoretical question but an absolutely real one with which GPs are likely to be faced if they have not been faced with it already.

(Prof Kennedy) It is by no means new, Sir David, in so far as when there is a spouse who is infected with syphilis or any other transmissable disease it is not uncommon for that to be passed on. I do not think that that is an impermissible breach of confidence.

1298. In that case, one is led to ask you this. As we know, the National Health Service (Venereal Diseases) Regulations 1974 provide the statutory requirement for confidentiality in the case of sexually transmitted diseases. Does this mean, therefore, that there is no guarantee of confidentiality for those who contract HIV infection through intravenous drug abuse or blood transfusion, since they would not be covered by the venereal disease regulations?

(Prof Kennedy) The venereal disease regulations, as I understand them, provide for exceptions, do they not?—that health authorities may be informed in circumstances where there is a need to prevent disease spreading. And there are certain other exceptions. I would then go back to say that, as regards your intravenous drug user who is infected, the ordinary principles of confidence apply: namely, that one ought not ordinarily to break confidence except if a good reason exists and can be shown to exist. One such good reason is where someone, clearly, in your calculation is at real risk. That has to be a risk to their health rather than anything else. And that will not be a very large category of people, although it will include the spouse.

Mr Winterton

1299. Is it ethical in your view to devise a programme of screening to obtain epidemiological data?

(Prof Kennedy) I am sure that it is appropriate to devise a scheme of screening. It may turn on what the scheme is or on the form of the scheme. If the form of the scheme is one which has been proposed, namely, prevalence screening by anonymising blood which has been taken for other purposes—in other words, as it were, rubbing off the name of the donor—and then testing it, I see a very strong case for doing this in so far as here is a disease, the exact dimension or proportion of which we do not know, and about which we need to know so that people like yourselves, the policy makers, may make appropriate plans. However, I see grave ethical objections to doing that kind of screening and, if I may, I shall briefly put them to you. They are that, first of all—and I think you may have received evidence on this—there may be scientific difficulties which suggest the invalidity of such an exercise; because the data collected will not be particularly specific or organised. For example, if you have rubbed out the name, as it were, and have collected this blood because the person was contemplating an operation for—let us imagine—ingrowing toenails, you will not know whether this person is an intravenous drug user or a homosexual, you will not be able to gather epidemiological data as to the leakage from certain groups into other groups—which, after all, is one of the things we need to do; and, if it is bad scientifically, then it is bad ethically, because you are doing something which, *prima facie*, invades the privacy of someone else for no good reason. But even if one could satisfy the scientific argument, I think that there are very strong objections to it—objections which persuade me, although they may not persuade others—because it means that for the first time we contemplate a system whereby we ask the doctor to be privy to a system whereby he or

[Mr Winterton *Contd*]
she forsakes the care of his patient; because by rubbing the name off, as it were—and I use the expression figuratively—he is no longer able to get back to that patient. One knows that he may not be able to care for the patient to cure but certainly can counsel, can advise and if the patient be—as Sir David mentioned—married, can appropriately advise. And it is not only the patient's interests which are violated; it is also that arguably society is not particularly benefitted, although that is the argument which is advanced—the individual against society. I do not think that society—if I may use that term—is particularly advantaged in two respects. First, because if we do not know who this is, we are, in a sense, perpetuating potential harm by allowing this person to carry on in the community as a potential donor or in risk when we could have known had we asked; and, secondly, because socially we are abandoning a principle about which we have always cared very strongly, that of voluntariness, the idea of not conscripting people but of having volunteers. And we are undermining the doctor/patient relationship with the possibility of those most at risk going underground. Those, in short, are my objections.

1300. May I finish the point I was making. I have been fascinated by the case that you have put forward and the points you have made. But, if one had ignored just one or two things that you had said, one would have believed that you were arguing for screening where the people who are being screened are being identified. You are actually arguing for screening whereby the person who has come in for just a general screening can be immediately and readily identified and treatment, counselling and you-name-it could then be given to that patient. Are we not doing that?

(Prof Kennedy) Mr Winterton, I think that if screening were voluntary and were accompanied by all the procedure of counselling and care which we know to be necessary, it would be an immensely important advance for us in dealing with AIDS. Therefore, screening, yes. But anonymous screening in prevalence studies, as has been contemplated, in my view, no. And I do not think that it gives proper respect to the citizenry for I am sure that most of them would volunteer if you asked.

Chairman

1301. How are we to get the urgent epidemiological data that we need?

(Prof Kennedy) I can answer in two ways, I suppose. One, the easier way, to adopt Mr Winterton's view which is to go out and ask and seek, using pregnant women as one class, and others. The second is to say—and this is to take, if I dare, a philosophical point—that there may be some things which one wants to know but, if the only route towards knowing them is an impermissible route, one may not know them. One may either have to try to find desparately another route, or simply operate somewhat in the blind. I know that that is an unhappy position for those who have to make policy but it is, after all, the heritage that we have acquired from Nuremberg and afterwards: that there are some limits to the pursuit of knowledge, one of which is that when the pursuit of knowledge so interferes with and violates certain fundamental principles which we hold dear, we simply cannot continue it.

Mr Yeo

1302. But even if you did use pregnant women, you would still have the problem—unless it were made compulsory—that there would be no scientific basis to the information?

(Prof Kennedy) I am not sure that that is right, Mr Yeo. Perhaps I am not putting my point clearly enough. I contemplate that if you ask and if you have a well organised questionnaire, previously thought through, so that you have the information you want, then, in those circumstances you have very sophisticated data and could check boxes and do that in a routinised way, asking the woman beforehand—and, let us imagine, most would volunteer—and you are beginning to develop data which you can then categorise properly.

Sir David Price

1303. But if this is to be done on a scientific basis, do we not, above all, want to try to get more knowledge of how far this disease is moving out of the identifiable risk groups and into the general population. Therefore, with respect to my colleague, total randomness over the whole population is, as yet, not as important as identifying the fringes of people moving in and out of the risk groups?

(Prof Kennedy) That is also my understanding, Sir David.

Mr Yeo

1304. Just to take up Sir David's point, how does testing pregnant women help those unmarried men? How, by testing pregnant women, do you see whether the incidence of the disease is or is not increasing among them?

(Prof Kennedy) You do not. I believe that we may be talking about two different things, I think that testing pregnant women is not random; it is obviously very concentrated and very specific. It would allow you to develop some data. It would not be the total picture. You may have to adopt also another scheme whereby, voluntarily, you can test other groups—and particularly young men who show up at—shall I say, off the top of my head?—student health centres. There is a good group of young men who may be middle class but——

1305. Of course, the likelihood of people opting out of the test becomes much greater. With pregnant women, I can understand that most of them would decide to participate. But if you take a bunch of students, I can imagine that a quite significant proportion might say that they would rather not take the test.

(Prof Kennedy) I do not know that. Unless it is tried, one can assert or deny that. It is simply unproved until one tries it. I happen to think that there is a greater reservoir of willingness to participate than perhaps has been hitherto assumed.

Mr Winterton: Following this up again, the Govern-

[Mr Yeo *Contd*]

ment's Chief Medical Officer indicated that there was random testing taking place when people went into hospital. But, of course, that blood sample was not identified to any individual. Unless you can contain those persons, counsel them, seek to give them the advice which means that they are not going to pass on the disease, what good is there in undertaking that sort of random testing when it is not going to give you the sort of guidance and data upon which you are going to be able to base any policy of seeking to contain initially and then to cure the disease?

Mr Yeo

1306. It only tells you about the spread.

(Prof Kennedy) It may not even tell you that. But, with respect, that is a question for an epidemiologist rather than for me. If I can put on my ethical hat, I would say that if it is bad science then it is bad ethics. There is other testing—people going in and asking for a test—which, if it is properly pooled, will give you some picture because you know who you are testing and what group they belong to. But the idea of a bit of testing here and a bit of testing there without any underlying thesis attached to it seems to me to be doing more harm than good.

1307. Pursuing the ethical point, if I may, but on a broader front, is it ethical for us to say, "We shall not try to seek to obtain more information about the spread of AIDS."? It is all very well to decry the anonymised testing and saying that it finds out only about the spread. Information about the spread would be of immense reassurance to millions of people in this country at the moment. What we do not know is about how rapidly it is spreading. There are all sorts of people who may be altering their behaviour patterns for no good reason. Not to seek that additional information is, by itself, perhaps an unethical position to take up.

(Prof Kennedy) With respect, no. I think that I would still hold to my view that, first of all, there is a scientific question to which I am not qualified to speak, but I have my doubts as to whether you will generate data which will help you as policy makers. But, secondarily, if I have not persuaded you I would still seek to persuade you that if the obtaining of that information so offends principles that we hold strongly, then we ought to think very seriously before we go ahead and we ought to think whether we cannot use some other method which involves people voluntarily rather than doing something in—

Mr Winterton

1308. Mrs Short mentioned pregnant women and we have talked quite a lot about the testing of pregnant women. Can I go back to before the occasion of conception. Would you go so far as to indicate in your view that all those intending to marry or to have children should be screened for this disease, and particularly—I add this—those who have reason to believe that the number of partners that they have had previously and their own individual behaviour may well result in their being in what we describe as a risk group?

(Prof Kennedy) I think that we, first of all, unwrap the question and separate marriage from child-bearing since, in our society, they are not entirely related to each other.

Mr Winterton: They should be!

Chairman: Then let us say, "who marry or who have children".

Mr Winterton

1309. But it does refer to an important point.

(Prof Kennedy) I am not taking that point but it is the case sociologically that they are not. But it raises the important point that if one is saying that this should be a precursor to obtaining a marriage licence, then perhaps it is not going to address the sort of problem that one wants to address—namely, the prevalence of this disease among people who have promiscuous sexual activities or, indeed, are of child-bearing age. If the question is, "Should one seek to obtain this information?"—the answer is, "Yes." If then the question becomes, "How do you obtain it?"—then I am going to ask you what method does one contemplate to obtain this information from young people who may be sexually active? If it is compulsory, then I think that there are difficulties on the level of practicalities: how are we ever going to police it and how are we ever going to enforce it; and are we not going to do that which is socially deleterious, namely, to drive these people away? If it be voluntary, then we are talking about what we have talked about already, namely, that one should seek to encourage all groups, particularly those who are sexually active, to have themselves tested and, possibly, re-tested at intervals.

1310. And, in particular, those who are considering having a child?

(Prof Kennedy) Indeed! And that should be part of the general drive which is, I take it, the present Government's posture—one with which, if I may say so, I entirely agree—that these are precisely the categories of people that one should encourage to come forward, thinking of themselves and of their potential children.

1311. Professor Kennedy, may I ask you an ethical question—and I hope that you will not consider it to be trivial or flippant. Dementia, I understand from our studies, could be one of the first signs of AIDS. Should, therefore, in your view as an expert in ethics, all responsible people not be required to take the test—particularly airline pilots—and I gather that quite a lot of them do so already—train drivers, politicians and even professors?

(Prof Kennedy) I have some initial hesitation about responding to that question, I think it is a very serious question. Let me generalise the question. It is really a question about testing people within certain categories of employment. As regards employment, there are major ethical problems having to do with testing, with which you, of course, are familiar. In fact, I think that it is one of the major areas of difficulty, whether it is testing before

[Mr Winterton *Contd*]

employing someone or testing while someone is in employment. Ordinarily, one would say that there seems to be no good reason why an employer should require an employee to submit to a test because, after all, the primary form of transmission of this disease is through sexual intercourse and there are not very many forms of employment that one could think about in which that was a necessary prerequisite. However, it is becoming clear that there are some early signs which could affect the job performance of the employee. You mentioned airline pilots or people with other responsible jobs. I think that it is a matter for the policy makers here to seek to identify whether they can set up guidelines for employment which will allow the avoidance of those risks to others without writing a prescription for potential discrimination against a whole range of employees where there is absolutely no risk related to the performance of their jobs. I think that it is a scientific matter to identify those who are risk-bearing—and of the epileptic truck driver we already know and, too, the examples that you gave—and to find out how great is that risk. I think that it is an important matter to work through guidelines with the CBI, with the TUC and so on.

Mr Yeo

1312. Given that you seem to have rejected the idea of anonymous testing on ethical grounds, if we then go down and find groups, whether pregnant women or students or whatever may be the groups who are appropriate and willing to come forward in large numbers, what are the implications when some of those are identified as being positive? What are the implications? Do they have a little card that they carry around or a thing that they stick on their heads? What do you think would be appropriate after that?

(Prof Kennedy) For those who are identified as HIV positive, the only response I can make is that it is appropriate to treat them as ill people like any other person who is an ill person. To adopt any other posture is merely to exacerbate the problems of discrimination that we have already encountered and to work against precisely what we are seeking to achieve, which mainly is to cause people to come forward so as to enable the development of this sort of information. If it be for a moment suspected that there is a consequence of the identification, that they are going to be stigmatised—and this means that, of course, you would have to consider employment, insurance, loss of property, being thrown out of one's flat, and so on—as a feature of encouraging voluntariness, then people will not volunteer. So that I think they can only be treated as ill people.

1313. But supposing that we have the principal of a university college where this testing is taking place on a large scale, is it not rather important information to people who are considering going to that college and forming relationships with people who are already there if 25 per cent of the existing students were found to be HIV positive?

(Prof Kennedy) My answer off the top of my head would be, if we use universities as an example—and I do not think that it is a bad example—that it would be inappropriate in those circumstances for any principal or anyone else to declare that to be the case. I would suspect that the risks are the same in the universities as elsewhere. Furthermore, it would be simply counter-productive again because people would not come forward. These are not ethical points but practical ones.

1314. Nevertheless, there are ethical implications for other people. Let us say that you discover that only one person is HIV positive. There are implications for the relationships which that person may form with other people and it seems to me that once you have got into this business of testing without the anonymous element to it, you raise so many other questions. I am not quite sure what is your view of the wider issues in all this.

(Prof Kennedy) Once you have identified someone, then there are contingent further risks which you have to address. The difficulty is that in addressing all of these you are, I think, affecting what system you can accept—and this is the first point—because if you attach contingent consequences which are adverse to the interests of the person, then he will not come forward. But you are quite right to say that there are responsibilities to others. My view is that the evidence I have from those to whom I have spoken—and you have spoken to far more—and from those who care for people who are identified as HIV positive is that their attitude is almost uniformly one of responsibility in terms of sexual relations thereafter. So that, if one perpetuates the posture which so far has been adopted, it strikes me that that is a problem that one really does not have to address with any great concern.

Mr Winterton

1315. Is that true in connection with drug addicts? It is not the fact that they take a more responsible attitude to physical personal relationships. It certainly is not.

(Prof Kennedy) Mr Winterton, you are right. The drug addict community is, if you will, separate from any other community. It strikes me that we need to do a great deal more work on finding out how drug addicts live and why, for example, they share needles. It may have nothing to do with the fact that they have not got needles. It may have everything to do with some kind of curious feeling of community. In those circumstances, I accept entirely your point and then say that I would withdraw what I said in part and say that we have to talk of two possible communities: those who are largely within our culture and are responsible and those who are, if you will, a sub-culture, who have, by their adoption of the use of drugs, in some way isolated themselves. As regards that community, I do not begin to know what are the answers. But I am sure that they do not lie in, for example, compulsory identification and locking up. I think they lie in some very deep, profound understanding of why people have recourse to drug addiction. AIDS, if you will, merely throws up the problems associated with drugs.

[Mr Winterton *Contd*]
Mr Winterton: But it is very dangerous, is it not? —because they do not, as I indicated, modify as it were their sexual behaviour. And they, like bisexual men, are very likely to spread it into the heterosexual community more rapidly than is the case with the straightforward homosexual community which, of course, very much looks into itself and looks after itself.
Chairman: But not all drug abusers are homosexual.

Mr Winterton

1316. No. That is the very point I am making. They are not homosexual.

(Prof Kennedy) I agree entirely that if one wants to think in terms of danger, the danger of spreading to the heterosexual community lies in the leakage—if I may use that word—from intravenous drug users. And, if that be the case, then I do not have the answer save to say, as a matter of ethics, that I think it would be inappropriate to have recourse to measures which were merely punitive, which merely have in mind some kind of compulsory isolation; because I do not think that they would work and I think that they are too invasive of personal liberty. For both of those reasons, I think we have to attack the drug addict as a problem which involves the understanding of drug addiction as well as many other things.

Sir David Price

1317. Is there not substantial evidence from California, who have had the longest experience in an advanced society of this epidemic, that the homosexual community have reacted and changed their habits a great deal more—and that there is a good deal of reason for hope in that area—but that there is no evidence that the intravenous drug abusers, the drug community, have altered their habits in the very least?

(Prof Kennedy) I think that is right, Sir David. The evidence is already available in this country of, for example, a decline in the incidence of sexually-transmitted diseases among the homosexual community. When we have a number of isolated communities of intravenous drug users, they, in my view, represent the major risk to the community. On them, I have very little to say, save to say that resort to compulsory methods of any kind historically have largely not worked because, historically, they have been counter-productive. The drug user is already underground. You merely drive them deeper.

Mr Winterton

1318. But, Professor, we are talking about a really serious disease, a plague disease, which could shortly reach epidemic proportions. Therefore, perhaps, we ought to think again about this sort of rather liberal approach—that we "cannot afford to drive them underground". But if, in fact, because of their continuing activities, they are threatening the nation at large, we have got to do something.

(Prof Kennedy) I understand the argument, Mr Winterton. I should not like ever to be accused of being liberal—

1319. With a small "l"?

(Prof Kennedy) Indeed! I think that the history of responses to plagues from the Middle Ages onwards would tell you that in all circumstances, on every occasion, recourse to the kind of compulsory isolation, compulsory police use and so on, have always failed historically—from the hanging of ten thousand Jews because they caused the Black Death in the Middle Ages to locking up the Chinese in Sydney with the outbreak of cholera in the 1890s. We have consistently gone through that route and it has consistently failed.
Mr Winterton: What about rabies? What do you do with people suffering from rabies?
Chairman: We are not dealing with rabies.
Mr Winterton: No, but this is important.
Chairman: We are not looking at rabies.

Mr Winterton

1320. I know. But that is a very serious, dangerous, killing disease.

(Prof Kennedy) I am not sure that there is any history of our locking up people with rabies. We certainly prevent them from bringing in animals.

1321. If people have rabies, we isolate them.

(Prof Kennedy) I am sure that the differences are significantly different. We isolate people with other illnesses also but largely for public health interests where we are satisfied that the contagion is very, very great. Here, in AIDS, the contagion is really not very great at all. By and large, it is possible to get it only through one of two means.

Mr Galley

1322. What about the Public Health (Infectious Diseases) Regulations which we passed two years ago. Do you think that we are likely to be able to implement those or that there may be circumstances where we might implement them?

(Prof Kennedy) To my knowledge, they have been used only once. It was in Manchester, as I understand it. One of the curious things about the regulations—and, Mrs Short, you perhaps can advise me more—is that they do not address the HIV positive person but only someone who has AIDS—which seems rather curious because it is the HIV positive person that one is as much concerned with, arguably, as the person with AIDS, the full-blown syndrome, if you will. It may be that one should have recourse to it from time to time. Probably the only argument that I can see is for the person who is identifiably HIV positive—and the regulations do not seem to cover that person—and who says, categorically, "I am not going to change my behaviour but I am going to avenge myself on others", that there is possibly a case for the police power. But, otherwise, I think it is part of the panoply of compulsion that in my view is, perhaps, going to be counter-productive. It undermines the notion of voluntariness which, so far, seems to be working.

1323. You do not regard compulsory hospitalisation as a back-up power to be necessary?

[Mr Winterton *Contd*]

(Prof Kennedy) I think that there is no reason why it should not exist. I think that there may be good reasons why we should not ordinarily use it. And I think that the power we have, with respect, is rather poorly drafted in so far as it does not speak to HIV positive but only to AIDS.

1324. Do you think that we ought to extend it to HIV positive in certain circumstances?

(Prof Kennedy) If, Mr Galley, you are contemplating having a reserve police power, you ought to have one that is appropriate to the task.

1325. What about screening people who have visited or are visitors from or are returning from a visit to a country where AIDS is endemic? I understand the ethical points that you have already put to us but would it be of value to say that there are certain countries in the world where it is so endemic that we must screen everybody when they come into this country?

(Prof Kennedy) I think that there are contingent factual problems here, are there not? It takes three weeks for the test to come through. What is one going to do with the person during that time? It seems hard to argue, with three Jumbos coming in from New York or San Francisco, that one could hold people at Heathrow. If one requires them to register with the police in three weeks' time, what has one achieved? They may have had sexual contacts in the interim. Again, I am not sure that it really would solve the problem that we are seeking to solve. It is a different approach to say that people applying for visas coming from other such countries should be able to demonstrate that they have had a test. But, of course, the problem with them is threefold. One, we know that you can acquire documentation as to anything if you really want it: two, the test is only as good as the last sexual contact; and, three, there is a sufficient proportion maybe of false negatives perhaps to suggest that we would not deal with the problem in any way satisfactorily through that route.

1326. It depends somewhat upon the definition of "endemic" but there are certain countries of the world where it would appear that the disease is more widespread even than in the United States. There are the practical difficulties that you have put forward but if a large proportion of people—let us say, 50 per cent of them—coming in from particular countries are likely to have AIDS, should we not try to overcome some of the particular problems at the point of entry to stop one possible source of the spread?

(Prof Kennedy) I would have to be persuaded, if I were a policy maker, that the risks were great enough to invade the civil liberties of those landing in the country, many of whom would pose no threat at all to the citizenry of this country.

Mr Lewis

1327. Is there a point, Professor Kennedy, beyond which it is not worth the time, money or effort spent in treating a terminally-ill, gradually-declining patient?

(Prof Kennedy) I would have to ask the question of what you mean by not treating. I do not think that a doctor should ever not treat. Better to say that the doctor changes his treatment from treatment for living to treatment for dying. And treating for dying contemplates less intervention and less a lot of other things, but certainly does not connote abandonment.

1328. And would you go along with that?

(Prof Kennedy) I think that that is the bedrock of modern medical ethics: that if you have a terminally-ill patient, at some point you are entitled to give up on intervention which may, indeed, be cruel, and comfort that patient and allow the patient to die.

1329. Euthanasia?

(Prof Kennedy) That is not euthanasia.

1330. I know that. I mention euthanasia. Would you go as far as that?

(Prof Kennedy) For my own part, I am not persuaded that we even need to consider euthanasia. If doctors are aware of their legal and moral obligations which are, in my view, to shift from caring for living to caring for dying when it is hopeless to continue to do otherwise, then there is no need to talk about euthanasia but merely to change one's care to comfort and to allow the patient to die with dignity. We do not need to talk about killing people.

Mr Lewis: I am with you on that.

Mr Galley

1331. Are we in danger of distorting the resource allocations within the National Health Service because of the preoccupation with this problem? Are we redirecting too many resources to AIDS when we have other diseases, cancers, heart attacks and so on, which affect far more people? Two or three weeks ago, we had an eloquent plea for additional resources for various aspects of coping with AIDS and those sorts of pleas are not unusual in this Committee.

(Prof Kennedy) Mr Galley, if I may say so, you are right to raise that. Whether it is too much is ultimately a question for you rather than for me. The question for me is to identify what criteria should be used in making decisions as to how much is the right amount. I think that those criteria are: what is the need? what is the benefit to be gained from putting resources into this rather than into something else? and what are the costs elsewhere if one does that? I think that if the cake remains stable, if you do not increase the cake, inevitably there are going to be opportunity costs elsewhere if you spend what is estimated to be £60 million within the next five years on caring for those who will fall victim of AIDS. It is a policy question for you, yourselves, as to whether you think it is justified to spend, given that the cake remains the same, money which otherwise would go to screening for breast

[Mr Galley *Contd*]

cancer or for cervical cancer or for the treatment of other illnesses. The possibility that there may be a major epidemic may persuade you that the need is so great and the benefit is such that you will re-allocate. But that is a question initially based upon a factual assessment. Only when one has the facts can one say, "Yes, it is large enough to displace our concern for others."

1332. If you were now the adviser to the Secretary of State and on the basis of the information that we now have, what—to put the ball into your court—would you advise him, in the context not that the cake remains the same but that the cake is actually growing all the time and that the demands to consume the cake are growing, if anything, at an even greater rate than the resources that can be allocated?

(Prof Kennedy) Let us assume, if you like, that there is a stable or slightly reducing cake. If that be the case, I, for my own part, think that one of the ways of assessing it is through the scale often used in the United States: the so-called YLL —"years of life lost". We are talking about young people who would be otherwise productive. That is a factor to be borne in mind. But it is equally a factor to be borne in mind in cancer of the cervix or in breast cancer.

Chairman

1333. And those are treatable and curable.

(Prof Kennedy) Indeed. I was about to say that, Mrs Short. But, given that there are responses available to these other diseases which are curative then I, for my part, do not necessarily see AIDS coming at the top of my shopping list.

Sir David Price

1334. Following up on that thought, also it can be that we are talking about AIDS treatment much more in terms of care in the community and going through to terminal care than we are in the sense of intensive hospital treatment. That, again, is more like the evidence from California.

(Prof Kennedy) That is the option now being preferred in California because it is more and more seen that one does not need this intensive, high-technology care, except from time to time, and many people are happier in the community. But, of course, community care in itself has its costs. I understand that the NHS save something of the order of £18 billion a year by having people look after other people in their homes rather than through the use of medically-qualified personnel. Those are costs, where that person might otherwise be working or doing something else. We ought not to put it out of account. But, even so, I think that that form of community care will take expenditure which we could put elsewhere.

Chairman

1335. Assuming that we have possibilities of preventing more cases of AIDS—and I am ever philosophical and optimistic—how do you think we should treat our children about this particular problem? How should we help them to avoid it?

(Prof Kennedy) I find this a very hard question. I would begin with the view that there are certain moral points to be made about the nature of sexuality if we are talking about sexual transmission. Equally—and I will put on one side the problem of drug use for a moment and deal with it a little later—there are certain moral points about sexuality which I think ought to be part of the education of any child. There may be differences as to how much one is committed to the notion of one partner always, ever, and how realistic that is. I think one of the arguments that could be advanced——

1336. Excuse me for interrupting you. When you say "one partner", are you including one homosexual partner, as well?

(Prof Kennedy) Yes, I am, for this purpose. One of the things that I think is missing from the present health education campaign is some context in which sexuality ought to be understood: namely, that one would aim for the restriction of or reduction in the number of sexual contacts. There is nothing wrong with that; and there may, indeed, be something right with it. Having said that, one then moves to the second position that, as the lawyer would say, if (which is denied) so-and-so is going to happen, then these are ways whereby you can protect others and yourself. We should seek to educate children in that regard. But I think that it is a two-stage process with the moral backbone coming first, before you come to the contingent safe-sex argument.

Mr Winterton

1337. Before you come on to drugs, which is really the second part of the answer that you are going to give, and to provide a balance to Mrs Short's question that she put to you initially, I hope that you would not suggest that in talking to young children one should actually talk about one homosexual partner. I would hope that we would be talking about one natural, heterosexual partner in life rather than seeking to inculcate into young people the fact that some people believe that homosexuality is equally as good as heterosexual relationships; or that lesbian relationships, for that matter, are as good as heterosexual relationships. I hope that you are saying that you would teach young people about one partner in life and that that should be a boy and a girl, a man and a woman?

(Professor Kennedy) Mr Winterton, I was not saying that. I do not want here to be drawn into making what I think are moralising statements rather than engaging in ethical analysis. I think that there is some danger in using the word "natural" in the context of sexual behaviour. If I may divert your attention for a moment, if one's condemnation of homosexuality is because it is unnatural, one has very great difficulty in defending opera singing.

1338. I think that that is quite natural. You do not?

[Mr Winterton *Contd*]

(Prof Kennedy) It is not a common or natural occurrence that we——

1339. Opera singing?

(Prof Kennedy) With respect, no. But, in any event——

1340. We seem to fund it very heavily in this country.

(Prof Kennedy) That may be the case.

1341. Some are suggesting that we fund homosexuality, as well, as are some left-wing authorities.

(Prof Kennedy) That being the case and not wishing to be drawn into points which are really outside my remit——

1342. They are ethics.

(Prof Kennedy) Your question was whether one should inculcate into young children . . . Mrs Short's question did not add the adjective, young, to what she was saying. I think that as children grow up, so they should be exposed more and more to the range of human behaviours and an understanding of the differences which exist between all of us. How one does that, of course, requires great tact. Whether one does that, I think is clear. One ought to do so. To respond to the question about drug use, I think that with children who grow up and become intravenous drug users, there has been clearly a familial break down already. To suggest that families can in some way address themselves to AIDS by saying, "If you become a drug user, which I hope you don't, then watch out for AIDS", then I think the question becomes, "Please, how can we organise our children so that they do not become drug users?"

Sir David Price

1343. May I move on and ask you what ramifications does AIDS/HIV positive and the issues it raises have for the legal liabilities of doctors and of other health care professionals?

(Prof Kennedy) I think that we will see within the not too distant future some action brought against a doctor if he or she does not advise, for example, a partner—as in your example, Sir David, earlier—because that may well be a negligence, a breach of the doctor's duty to a patient, if the spouse be his patient. I foresee that happening and I should have thought, if the doctor pleads that he is confidentially bound not to disclose that, that it would be unlikely, in the circumstances—and here I am engaged only in prediction and may be as wrong as anyone else—that the court would hear that defence and would say that this is so serious, that there are such risks involved, that the doctor really ought to have told someone else who was at risk. That would apply to all of those categories where they may be real risk to health if the person is not advised.

1344. May I follow that up with a specific example among doctors? You have a practice. I will not identify it. One partner refuses to make a note on the person's records that he had AIDS because he was afraid of it being read round the surgery. It is a group practice and he is off duty. One of his partners is called out, picks up the case notes, which are therefore incomplete and from which the most important piece of information is missing. That partner, therefore may give the wrong treatment or whatever.

(Prof Kennedy) The second doctor is at risk only through a needle stick or cutting injury.

1345. I do not mean that he is personally at risk.

(Prof Kennedy) Let us separate the people who may be at risk. The second doctor, I think, would not be able to complain in law on the grounds that all doctors now should assume that they should take all precautions in terms of the use of sharp instruments with any patient. If, on the other hand, he counsels this patient in ignorance to do something which may endanger a third party, and that third party is known to him and to the other person, then I think there would be liability on the first doctor.

Mr Winterton

1346. What about the danger to the patient himself or herself if he were to give a wrong diagnosis or medication?

(Prof Kennedy) It would follow always if one doctor has failed to note something which puts another doctor at a disadvantage. This is not specific to AIDS. It would be a general proposition.

Sir David Price

1347. That brings me back to my "need to know".

(Prof Kennedy) Quite so, Sir David.

1348. And to the risk that his partners in the practice who are liable to take up the notes are ill-informed.

(Prof Kennedy) I think that this is merely an example of a general proposition that doctors should ensure that those who come subsequently to treat the patient know, for example, that he is allergic to penicillin. That would be a good example. If that is not noted and subsequently the doctor treats in ignorance of that, then the first doctor is clearly liable in my view. That would apply here. If the doctor is concerned about the leakage of information to others, then that calls not for suppressing the information in the records but for having a better record system.

1349. The other aspect is this. If a doctor finds a person is seropositive, we know from other diseases that are liable to be terminal that some doctors, perhaps according to the psychology of the patient, will take a long time to tell the patient or may even not tell the patient. They have a right to know. What is the position here? Could the partner of a patient come back to the doctor and say, "You didn't tell *X*" But the doctor in this clinical judgment had decided that *X* was not psychologically ready to be told.

(Prof Kennedy) I think that the management of the individual patient may well have to take second

[Sir David Price *Contd*]

place to the putting of other people at risk. If it be the case that you choose to manage the patient in a way that puts others to risk, then you may well face legal liability as a consequence.

Chairman

1350. This is the last question that we have for you. What would be the position if someone passed on the infection knowingly? Would he or she be liable at law?

(Prof Kennedy) I think that there is now a strong argument to say that the is the possibility of a suit both in tort—the tort of battery or of negligence —and there could be also the possibility of criminal prosecution. Some people in the United States—and there is an important recent set of papers in the Hastings Centre Report which discusses this at great length—argue that you should not have recourse to the criminal sanction here for the other reasons that we have already mentioned: the contingent reasons of driving people underground and so on. I think that it is a possibility that someone would be liable under the Offences Against the Person Act and that, as Mr Galley was asking me earlier, that this should not be overlooked as a possibility but should be considered only as a remote possibility where someone clearly is hell-bent on putting others at risk.

Mr Winterton: What about prostitutes?

Chairman

1351. That, of course, could apply to homosexual relationships as well as heterosexual ones, could it not?

(Prof Kennedy) Yes, Mrs Short. Mr Winterton asked about the prostitute. I think, again, the possibility exists but I, myself, would say that throughout the process of coming to terms with AIDS, let us try the voluntary approach. In my view, it is probably more justifiable to have recourse to educating others about recourse to prostitutes and educating prostitutes that it is in their own interests and in the interests of others to use condoms or whatever. Why then have recourse to police power? There is no historical evidence to say that locking up prostitutes prevents other prostitutes emerging.

1352. And you think that the condom message is getting through, do you?

(Prof Kennedy) I cannot answer that save to say that in my small sample, anecdotally, of my students, I am impressed by the extent of their knowledge and interest in this area. But they are a cross section of educated and intelligent people.

1353. Thank you very much, indeed, Professor Kennedy. We are most grateful to you.

(Prof Kennedy) Thank you.

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