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Haemophilia Action UK

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PLEASE TREAT AS PRIVATE AND CONFIDENTIAL

RE DAVID OWEN, GOVERNMENT DOCUMENTS AND SELF-SUFFICIENCY

Dear Ms Cooper,

I was recently sent a copy of letter from yourself to MP Paul Goggins by one of his constituents on the subject of David Owen, self-sufficiency, and haemophiliacs becoming infected with HIV and hepatitis viruses through contaminated blood products. You may have heard my name (Carol Grayson) mentioned as a campaigner on this subject. If not then I write to inform you that it was at my request that Louella Houldcroft of the Newcastle "Journal" interviewed Lord Owen last year with regard to his involvement with this issue as Health Minister in 1975. (I enclose Louella's excellent article in case you have not seen it). I originally contacted Lord Owen after obtaining copies of a series of his letters where he wrote to Government in 1987 in support of HIV contaminated haemophiliacs calling for an investigation and stating his belief (documented) in a meeting with legal representatives that the Government was "culpable" with regard to the contamination of haemophiliacs. As Health Minister at a crucial time in the history of haemophilia treatment many believe that he was in a prime position to know whether or not the Government needs to accept responsibility for its actions (or lack of them). As I am sure you are aware he was eventually told his files had been "pulped". I wrote to Lord Morris (a long-time supporter of the HIV/hepatitis C campaign for justice) on this issue who recently received a reply from Lord Hunt and I understand that this matter is now being investigated.

I have been warned by a senior member of the medical profession that by campaigning on this subject I am "opening up a can of worms and may receive death threats", also that "attempts may be made to discredit you". The consultant himself had this experience, this was echoed by yet another doctor who was also threatened. I have informed our solicitor that in the event of anything untoward happening to myself or my family the police are to be informed immediately to investigate and access will be given to my files, there are copies in several locations.

I write to request a meeting with you at your earliest convenience, along with Alan Milburn, supporting MPs and named representatives of the haemophilia community. I am sending copies of this letter to my MP Jim Cousins and to members of the campaign group recently set up within Westminster to support Haemophilia Action UK as well as to selected media. I wish to inform you that since meeting with Lord

Hunt last year I have accessed a large number of confidential Government documents on this subject including Treasury, Civil Servant, Public Health Laboratory and BPL documentation which in my opinion and in the opinion of many others shows incompetence and negligence with regard to ensuring safety for recipients of blood products. What is disturbing is that some of the information comes from the "inside" from persons within the system who feared for their own safety in passing on such information, therefore as you can imagine they would not disclose any of their personal details.

One of the first questions I would like to ask you is how do you intend to examine all the relevant documentation with regard to Lord Owen if his files have been "pulped"? Haemophiliacs DO NOT want an inquiry behind closed doors, we want a PUBLIC INQUIRY, after all Mr Milburn has been very vocal on a new transparency in the health service, openness and honesty, surely this includes issues related to the haemophilia community. We also believe that the information we hold will be enough to support Lord Owen's claims despite his files being pulped! Please note that Lord Owen promised self- sufficiency on the grounds of SAFETY in his words "whatever the cost". He recognised and spoke of the far higher level of hepatitis risk associated with imported blood products. As you point out with regard to production levels according to your records "the target was achieved within the timescale envisaged by Lord Owen," If this is correct I would like to know, why did this NOT carry on once Lord Owen left for the Foreign Office? The timescale set for self-sufficiency was 1977 at the latest. Why did the Government choose to expose haemophiliacs to a far greater level of hepatitis risk from imported plasma, when the Government and professionals were well aware of the dubious sourcing of plasma as documented in many medical journals, books and studies by hepatitis experts in the 1970s? (We also hold plasma company documentation and eye-witness accounts of safety violations with regard to collecting plasma in the US.)

Politicians appear to have a selective memory with regard to this subject, I would like to jog the Governments memory. Please note the following.

"At a meeting of the Expert Group on the treatment of haemophilia held at the Department of Health and Social Security on 20th March 1973 the Department was advised that the United Kingdom should aim to become self-sufficient in blood products AS SOON AS POSSIBLE by increasing lone production of freeze dried AHG concentrate. At the said meeting it was further agreed that 400,000 donations would be required to treat persons suffering from haemophilia. At the end of the meeting the said Department was advised that there was a pressing need to increase U.K. production in order to reduce and end AS SOON AS POSSIBLE purchase of blood from foreign sources".

"That advice was accepted by the Department who set out a memorandum to Regional Administrators dated 24th December 1974 that the Department regarded it as of THE GREATEST IMPORTANCE that the NHS should become self-sufficient as soon as practicable in the production of PPF and other blood products. In the memorandum the Department accepted the responsibility for co-ordinating a programme for the increased production of blood products, WITH THE PRIMARY AIM OF MAKING THE NHS SELF-SUFFICIENT IN AHG CONCENTRATE IN 2 TO 3 YEARS."

"At all material times the Department Of Health KNEW there was a very substantially increased risk of disease from blood obtained from paid donors compared with blood from voluntary donation."

"By a file note dated 29th November 1976 the Department through Mr Clearsby repeated that it was Department policy that all human products for the NHS should be produced on an "in-house" (i.e. NON-COMMERCIAL) basis"

"By the submission prepared by the National Blood Transfusion Service for consideration by the Royal Commission on the National Health Service in May 1977 the Department repeated that it was its fixed intention that the United Kingdom SHOULD BE SELF-SUFFICIENT within the NBTS and central Laboratories for the production of fractionated blood products. In the same document the Department identified 2 major defects (both of which were within the Department's power to cure or make representation on) in the NBTS being,

1) LACK OF FINANCE: the discrepancy of 100% between England and Wales on the other hand and Scotland on the other being noted:
2) LACK OF INTEGRATION between the Regional Transfusion Centres: the blood collection, fractionation and supply should be a national service."

There is a lot more documentation along the above lines!

Why given the huge known risks associated with imported plasma was it ever introduced in the first instance? This was madness! The importation of plasma in 1973 was licensed for import but was NOT licensed on the grounds of safety and did in fact directly conflict with advice from heptologists in the U.S. who were themselves concerned over the hepatitis risk associated with U.S. blood products. One world- renowned hepatitis expert Dr Garrott Allen even wrote to William Maycock, head of our Blood Transfusion Service strongly advising the UK NOT to import blood from the U.S. The World Health Organisation advised AGAINST using plasma from remunerated donors and stated that if you have a country with a low incidence of hepatitis (such as the UK) governments SHOULD NOT IMPORT from a country with a higher incidence of hepatitis such as the U.S.

The following was published in 1975.

" Most plasmapheresis donors are poor people from underdeveloped countries. Within the U.S., most plasmapheresis donors also come from the poorest segments of society- skid-row denizens, prisoners and the poorly nourished.

Blood banks, drug firms and hospitals compete for the exclusive bleeding rights among prisoners and the poorly nourished: those who participate receive special privileges or remission of sentence (in Massachusetts, for example, a prisoner's sentence is reduced five days for each pint of blood donated. According to the World Health Organisation (WHO) "poorer people who can, for health reasons, least afford to part with their blood are encouraged to give blood for the benefit of wealthier populations."

Many plasmapheresis donors support themselves exclusively by selling their blood. In the U.S. they receive $5 to $25 a pint (one plasmapheresis center in Miami advertises, " earn up to $2oo a month in your spare time"). Bur blood banks (U.S.) SEEK MOST OF THEIR SUPPLIES from Third World Countries, where donors are paid only one or two dollars a pint. In South India, some 40,000 people maintain

themselves by selling blood. Last May, WHO, urged its member countries to stem "the extensive and increasing activities of private firms in trying to establish commercial blood and plasmapheresis projects in developing countries." WHO recommended establishing national blood services based on VOLUNTARY, NON-REMUNERATIVE DONATIONS.

The commercial blood trade has for years been beset by a major health hazard, - high incidences of serum hepatitis, a debilitating and often lethal disease for which there is no vaccine or cure. Serum hepatitis can be contracted from the whole blood or plasma of a donor who has either had the disease or has lived where hepatitis is prevalent".

The Government also ignored its own advisors within this country NOT to use blood from remunerated donors. Not only did the U.S. have a higher incidence of hepatitis in the general population but as the article documents, plasma was routinely taken from skid-row centres, underdeveloped countries and in particular prisons where the hepatitis risk could be up to 70% higher.

If you look at the study of heat-treatment, this started in the 1950s and one of the questions being raised legally now is why companies placed an unsafe product (factor concentrates) on the market BEFORE putting money into research to eliminate hepatitis, the biggest known health risk post –transfusion, (KNOWN ABOUT SINCE THE 1940S). It appears that this decision was largely one of cost effectiveness as opposed to lack of technology with the development of heat-treatment in the 1960s and 1970s temporarily "shelved". Once the decision was made to whole-heartedly develop a method of eliminating hepatitis around the time of the emergence of HIV when the plasma companies knew they now had no choice but to act it took only 18 months to develop!!!!!!

In the early 1970s patients went from a small hepatitis risk using British cryoprecipitate, where patients were only exposed to a very small number of donors to huge plasma pools of up to 60,000 (often high-risk) donors, a PHENOMENAL hepatitis risk which was NOT divulged to the patient allowing haemophiliacs to make an informed decision on treatment risks! Shortly after imported products were introduced researchers noticed a marked increase in hepatitis B, and also non -A, non-B in haemophiliacs (now known as hepatitis C) which they were able to identify by elimination of other strains. This increase was directly linked to the imported factor concentrates. You will no doubt be aware of the House Of Lords ruling that patients must be informed of medium to high risks associated with treatment. This did not happen. Incredibly haemophiliacs were still being told by the national Haemophilia Society minuted in 1991 that hepatitis C was not a problem, this attitude continued up to 1994, this was also echoed by the medical profession and the legal profession.

You talk about a huge rise in the demand for clotting factors in the 1970s. Many patients at the time were surprised to find that their treatment regimes changed on the advice of their clinicians who went from prescribing 250 units to treat bleeding episodes to prescribing increased doses (prophylaxis) plus increased units for bleeds. Given the severe problems at BPL one has to seriously question the wisdom of such extreme changes, it seems totally irresponsible raising the levels of treatment for haemophiliacs at that time given that the UK's production facilities had been allowed to decline to such a deplorable level. The UK seriously failed to keep production facilities up to date and failed to meet even basic safety requirements (SEE QUOTE BELOW). To blame increased demand on haemophiliacs, (something which is frequently bandied about by Government) who were advised by their doctors on their

levels of treatment and told only the benefits of factor concentrates is not only cruel but also UNETHICAL!

(At this point I would like to state that the national Haemophilia Society has not and does not represent many haemophiliacs viewpoint. We have often found their information/advice inaccurate and are aware of the funding they receive from the plasma companies responsible for violating safety procedures leading to mass contamination. In official reports haemophilia societies across the world have often been deemed to have a conflict of interest and seen as NOT the most appropriate body to advise on safety of treatment. Haemophiliacs are currently challenging instances where completely incorrect information has been passed on to the haemophilia community. I do not include Lord Morris in this criticism as he personally has worked tirelessly for justice for haemophiliacs and is not involved in the day to day running of that organisation).

The following is taken directly from a letter from the Dept of Health and Social Security to the Treasury. (July 1981)

"Although BPL'S production has increased steadily over the years and is currently worth about £11 million a year to the NHS, health authorities are obliged to supplement supplies from BPL with expensive and, BECAUSE OF THE HEPATITIS RISK, LESS SAFE IMPORTED COMMERCIAL BLOOD PRODUCTS at a cost of £10m annually."

"In 1979 the Laboratory was inspected by the Medicines Inspectorate. The gist of the Inspector's report was that conditions of manufacture at BPL were UNSAFE AND POTENTIALLY HAZARDOUS TO PATIENTS. The report concluded "If (BPL) were a commercial operation we would have no hesitation in recommending that manufacture should cease until the facility was upgraded to a minimum acceptable level."

THE ABOVE IS RECORDED IN THE GOVERNMENTS OWN DOCUMENTATION.

HAEMOPHILIACS DEMAND A PUBLIC INQUIRY into why blood facilities and production were allowed to decline to unacceptable levels so that haemophiliacs were not catered for with regard to self-sufficiency in blood products in the UK as promised in a parliamentary commitment in 1974 but were forced to rely on unsafe imported products. We demand to know the names of those who made the decision to import factor concentrates in 1973.

With regard to HIV infection in haemophiliacs a letter from the PHLS Communicable Disease Surveillance Centre in London was sent to Dr Ian Field at the Department Of Health, in May 1983. The advice in an attached paper was as follows,

"The temporary withdrawal of all blood products imported from the United States of America made from blood donated after 1978 is proposed until the risk of transmission of Acquired Immune Deficiency Syndrome (AIDs) becomes clarified." It urges that an early meeting be called with haematologists, virologists, and others concerned so that a decision may be made as soon as possible.

(As documented in the PHLS paper, see below)

"REASONS FOR WITHDRAWAL OF BLOOD PRODUCTS"

1. The AIDS epidemic in the USA is probable due to a transmissible agent.
2. The agent is probably transmitted by blood and blood products. In the Lancet of 20th April, 11 cases of AIDS in haemophiliacs in the USA receiving factor VIII concentrate were reported, 3 in Spain also receiving factor VIII (confirmed by telephoning Ministry of Health, Madrid) and a case in a child following multiple transfusions is described. (One of the blood donors to this case developed AIDS 7 months after donating blood and died of the disease 10 months later). On 1st May the "Mail On Sunday" reported 2 cases in haemophiliacs in the UK: one of these, Professor Bloom's case in Cardiff, fits the accepted criteria of AIDS and had received USA factor VIII concentrate: we have not yet been able to identify the other possible case.
3. Although this number of cases of AIDS associated with the administration of factor VIII concentrate is very small in relation to the number of individuals receiving the product, this may NOT indicate that the risk is small because a) the earliest cases of AIDS reported in the USA developed symptoms in 1978 and therefore USA blood products manufactured from donations before 1978 are very unlikely to have been contaminated. Indeed the earliest reported date of onset of AIDS in a haemophiliac is October 1980. Most of the reported cases of AIDS have been diagnosed in 1981 and 1982."

HAEMOPHILIACS DEMAND TO KNOW WHY THE WITHDRAWAL OF BLOOD PRODUCTS MADE FROM US BLOOD DONATIONS PRIOR TO 1978 WERE NOT WITHDRAWN ON THE GROUNDS OF SAFETY? I REMIND YOU THAT THE PARLIAMENTARY COMMITMENT TO SELF-SUFFICIENCY IN THE UK SHOULD HAVE BEEN COMPLETED AT THE LATEST BY 1977 AND PROBABLY BEFORE THAT DATE! IF THIS PROMISED PARLIAMENTARY COMMITMENT HAD BEEN CARRIED OUT THERE WOULD HAVE BEEN FEW CASES OF HIV AS WAS THE CASE IN OTHER COUNTRIES THAT ACHIEVED SELF-SUFFICIENCY IN THE 1970S.

The Government states that all the information is in the public domain yet I remind you that with regard to the initial litigation over HIV infection the Government claimed "PUBLIC INTEREST IMMUNITY". Why, so they could hide the truth? Where can we access all this information now if it is in the public domain? The Government only offered an ex-gratia payment after lawyers for haemophiliacs legally overturned this decision, the government settled and the files were never opened up in court. This was of course before haemophiliacs knew of their infection with a second life-threatening disease, hepatitis C. A recent parliamentary question produced information that 99% of haemophiliacs infected with HIV are co-infected with hepatitis C and many other haemophiliacs have single hepatitis C infection! Could this be HIV infected haemophiliacs were forced to sign away any legal rights to litigate for hepatitis C infection even though at the time of the signing haemophiliacs were unaware that they were infected with hepatitis C! How can all the information be in the public domain if Lord Owen's files which he wished to access in 1987 in support of haemophiliacs claims have been "pulped". The Government is talking in riddles here!

The Government should be aware that haemophiliacs can and will if necessary pursue a criminal investigation into contamination issues as they have done successfully in other countries. We feel that there is now enough evidence to do this combining files on the Governments failures in this country with detailed evidence of gross violation of blood safety procedures in the States. This issue is far from dead and buried. More and more people are speaking out, as a forthcoming documentary to be screened here and in the U.S. will show.

The only honourable thing for the Government to do now is to hold up its hands (as the Japanese Government did) and apologise to haemophiliacs for the mistakes, which have been suppressed by successive governments. This has already happened in other countries. Haemophiliacs demand justice in the form of 1) A FULL AND OPEN PUBLIC INQUIRY, 2) RECOMPENSE ON A PARITY WITH PEERS IN EIRE and 3) THE SAFER RECOMBINANT TREATMENT FOR ALL HAEMOPHILIACS.

The haemophilia community have been experimented on with regard to treatment in a very similar way to the treatment experiments I learnt about on my visit to Auschwitz. In the U.S. and the UK as in Auschwitz largely untested treatment with high-risk factors was tried out on a community with disabilities with a total disregard for human life. The contamination issue is referred to in the U.S. as the "haemophilia holocaust". Haemophiliacs were the canaries in the coalmine, exposed to treatment where the risks were well documented in medical papers but this information particularly with regard to the dangers of sourcing of plasma from prisons etc was never passed on to haemophiliacs so that they could make an informed choice on treatment. Please do not insult my intelligence by coming up with a crass remark such as the Government normally does "but haemophiliacs needed this treatment". My partner a severe haemophiliac (less than 1% clotting factor) has been on treatment strike refusing factor concentrates in protest at both the exploitation of remunerated donors and his own infection with HIV, hepatitis B and C and exposure to v CJD for over two years now; his brother also a haemophiliac died of AIDS.

I look forward to your reply and await a date for a meeting. My partner is now in advanced stage liver disease due to hepatitis C, I feel that I have little to lose in speaking out. I feel it is my duty to ensure that all the relevant documentation which myself and others hold is released into the public domain to ensure that this awful chapter in history is recorded ACCURATELY, in Lord Owen's words this tragedy was "avoidable".

Yours sincerely

Carol Grayson (Haemophilia Action UK)