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Les Ulis, 4 December, 1991

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Dear colleagues and friends,

Blood Transfusion in France is in the midst of an unprecedented and profound crisis generated by an intense media campaign focused on the HIV contamination of hemophiliacs in this country.

Dr. M. Garretta former head of the Centre National de Transfusion Sanguine (CNTS) and Secretary General of the International Society of Blood Transfusion, Dr. J.P. Allain former head of the R & D on coagulation factor concentrates in the CNTS, as well as two high ranking officials of the Ministry of Health, Pr. J. Roux former Director General of Health and Dr. R. Netter former Director of the National Health Laboratory, have been officially accused and charged with negligence and fraud, and will stand trial following a two-year investigation by the French Department of Justice.

The media campaign which has been running for two years but has reached a climax over the last few months, is based on several allegations :

- Refusal of the French government and its advisers (mainly but not exclusively the CNTS) to import large quantities of heat-treated factors VIII and IX of commercial origin in 1985 (the importation being restricted for use in HIV-negative hemophiliacs).
- Delay (July - October 1985) in forbidding the use and withdrawing un-heat-treated coagulation factors manufactured by fractionation centres in France.
- Delay (April - May 1985) in introducing heat treatment technology in fractionation centres in France and especially in the largest one, the CNTS.





Two other important factors have played a major role in the present crisis :

- the allegation that French government officials delayed the approval of the Abbott (USA) HIV test for several months in 1985 so that the French test could be released first or at least simultaneously ;
- the structural, developmental, and financial turmoil which the CNTS has been faced with since early 1991.

The possibility of charging other national personalities from the political arena and the transfusion system including myself cannot be ruled out and it is alarming that the judicial investigations have not been carried out by experts in medical and scientific fields.

Encouraged by several high ranking international scientists, I have written the enclosed "Plea for reflection" which has just appeared in the December 3 issue of the Journal Le Monde in France.

If you share its message, I should be grateful if you would make known your concern and approval by returning to me the enclosed form by letter or fax. I intend to publicize your support once a sufficient number of signatures is attained.

I should also be obliged if you could kindly duplicate and diffuse my "Plea", the reply form, and the present letter among your colleagues, physicians, health care workers and Blood Donor Associations in order to provide greater support to this action.

As you can see from my text, I am not defending one party against the other but am trying to urge the Justice Department officials that the case must be examined by competent experts.

It seems to me that in such a profound crisis, each citizen and professional has the obligation to think, to look for information and to act. The present action, to which I am inviting you to participate, is in line with this moral obligation we have towards the Society and Blood Donors. ||

With best regards.

Yours Sincerely,

French Donor Assoc.

GRO-C

Dr. Bahman HABIBI

Encl.



A PLEA FOR REFLECTION

Bahman HABIBI

In the past six months, France has passed through a period of crisis unprecedented in the history of blood transfusion and public health. It has been a singular and destructive crisis, yet it has also been instructive and brings a promise of hope.

1 - THIS CRISIS IS SINGULAR IN SEVERAL WAYS

11 - Three entirely separate, complex, painful technical issues have been deliberately combined in their presentation to the public :

- The infection of haemophiliacs by the AIDS virus, which calls for a searching medical, scientific analysis.

- The date when routine anti-HIV screening of all blood donations in France was first introduced, which relates to administrative, decision-making procedures.

- The problems involving the structure and interaction of the National Foundation for Blood Transfusion and French blood transfusion as a whole, which are matters of organisation, strategy and management, on the one hand, and, on the other, of the changes needed to adapt our transfusion system to the Europe of 1993.

It is the moral duty of every citizen and all the information media, to treat each of these issues separately. My own appeal concerns only the first of these, the trigger - infection of haemophiliacs.

12 - Amongst the countries affected, some more extensively than France, by the tragedy of the haemophiliacs, we are the only country in the world where this suffering has created such a storm of media and political attention. **This singularity should give pause for reflection, and it would be salutary for our society to analyse its underlying causes.**

13 - The infection of the haemophiliacs is an extremely complex issue, and it raises numerous technical questions : In 1985, what was the perceived risk to haemophiliacs and patients receiving transfusion ? How were the very real dangers of hepatitis and circulating inhibitors to be weighed up against those of HIV infection ? How well did physicians communicate with their

patients ? How did the French transfusion and fractionation centres act, overall ? Did other developed countries act more slowly, more quickly or with greater uniformity than France ? Was hesitation or indecisiveness among physicians confined to France, or was it global ? What was the role of un-heat-treated products from the commercial sector imported in France during the 1980-1984 period ? Was it not then generally feared that heat-inactivation might create neo-antigens as in the case of recombinant Factor VIII today ? Had the efficacy of heat-inactivation techniques been validated in vivo, at the time ? Was it not the case that the risks inherent in plasma from paid donors were known to be greater than those from voluntary donors ? Were heat-treated products manufactured from HIV negative donor plasma really available for importation in quantities sufficient to cover the needs of France ? How many haemophiliacs have actually been contaminated by the domestic un-heat-treated products used in France between April and September 1985 ? Would we not have regretted the transmission of infection to other haemophiliacs by poorly heat-inactivated foreign imports ? etc. **Without in any way denying the errors of perception and the delays prevalent at the time, which I recognise with humility, it does appear to me to be inconceivable that justice will be done in France, unless the technical aspects of this complex case are submitted to the scrutiny of a national, or indeed, international group of physicians and scientists. The interests of justice require it.**

2 - THIS CRISIS IS DESTRUCTIVE IN SEVERAL WAYS

Blood donors are developing doubts and are being demotivated. The fundamental basis of blood transfusion in France, hitherto one of the forerunners in the world, is therefore threatened.

Members of the technical, medical, scientific and administrative staff are beginning to leave transfusion centres, and those who remain are anxious about their profession and their own future.

The image presented by French blood transfusion and medicine abroad is changing, and specialists in other countries are amazed by these events.

3 - THIS CRISIS SHOULD REMIND US OF THE EVIDENCE

31 - It may take months or years before any scientific discovery can be confirmed or validated, and the history of science is full of such examples. For every brilliant discovery which is confirmed, dozens of others fail the tests of time and further inquiry. Verification and documentation by other research workers is indispensable, but this process

takes time. Science gropes its way forward. The frontiers of ignorance are slow to retreat. It would be a salutary lesson in humility for those, fortunately rare individuals, who have forgotten their own doubts and uncertainties of the time, to scan the international scientific literature on the pathophysiology of AIDS between 1983 and 1985.

32 - Before any scientific discovery actually leads to public health policy decisions, years or even decades may pass. This is a fact. The history of medicine is illustrated by thousands of examples such as the discovery of streptomycin and its use in tuberculosis, the discovery of the carcinogenic effect of cigarettes and anti-smoking campaigns, the discovery of the Hepatitis B virus and the application of routine screening tests to all blood donations. With regard to AIDS and the safety of the blood supply, the time elapsed has been extraordinarily short : the virus was isolated towards the end of 1983, validated antibody screening techniques were developed and produced on an industrial scale by the first quarter of 1985, and applied in France in the third quarter of 1985 : a performance which is surely unprecedented in the history of medicine and blood transfusion, even if, in hindsight, one may regret not having reacted more rapidly or more decisively.

33 - In other developed countries where industrial coagulant factors are utilised, the situation of haemophiliacs has been as bad or worse than it has been in France, when those products were derived from the plasma of paid donors. It is difficult to imagine that tens of thousands of doctors and scientists, the world over, have been inadvertant accomplices in infecting a population of patients who have benefitted so greatly (at least in France and certain other European countries) from the solidarity of blood donors and the extraordinarily efficient support provided by the Society.

34 - The expectation that any effective therapy can be entirely free of risk is a utopian dream. This was true of blood products in 1985, and it still remains true today. It has always been incumbent upon physicians and transfusionists alike to carry out a risk/benefit analysis for every therapeutic procedure applied to individual patients.

4 - FINALLY, THIS CRISIS BRINGS A PROMISE OF HOPE

- The establishment of a legislative framework, in France, for **no-fault compensation of those who are injured as a result of medical treatment**, is now irreversible. Its rapid implementation will call upon the intellectual, social and media resources of this country.

- Health is a first priority for every French citizen. Our healthcare system is still one of the best in the world, although, in common with all human endeavour, it suffers from certain gaps. It must be adapted to the needs of modern society, and it must be given the means to meet those needs. One of these means is **to reform the process by which public health decisions are made. This is urgent.**

- We have been taught, in the course of our training, how to reach a diagnosis, how to initiate treatment, but never how to overcome barriers to communication with our patients. **Communication in medicine, is a developing science ; It is an art which can be learned. In this cardinal, but neglected domain, we have much to reflect upon, to research, and to teach.**

- The information media have played a determining role in the current events. The benefits of their campaign are real, but so are their errors and the wounds they have inflicted. **Public information and education must be a first priority of modern societies as we approach the end of the century. The media are its instruments and they must exemplify its highest aims, but they must also learn to find a way of increasing the benefits whilst they mitigate the damage they can cause.**

- The fundamental lessons I have learned from blood transfusion are scientific humility and human solidarity. The current crisis has done no more than to amplify those lessons.