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RISK AND CRISIS MANAGEMENT IN FRANCE : THE HIV/BLOOD CASE

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Now, in February 1999, the question of success or failure in decision-making is being judged in a penal trial by a special court created to judge members of government for action they took during office. Three former ministers including the Prime Minister are accused of manslaughter *(homicide involontaire)* for their decisions and non-decisions during 1985, when HIV transmission through the national blood transfusion system had to be stopped.

A further penal procedure is still pending. More than thirty experts, doctors and government advisers have been under legal inquiry since 1995, most of them for poisoning. The judgement in the ministers' trial will probably influence the extent of further prosecution.

As this procedure is currently in progress, it would be inappropriate to come to conclusions on the subject at the present moment. This contribution is therefore in two parts. Part I will isolate key elements relevant to the question of governance and suggest elements for discussion. The HIV/blood story itself is presented and analysed in Part II which was written beforehand[1] but still remains valid in its content (it may be easier to read Part II first). The definite version of a new paper will be written at the close of the ongoing trial and submitted in May.

PART I

1. Policy success and failure within a "long term crisis"

The French HIV/blood crisis became obvious when cases of death swept through the haemophiliac community, a long time after the risk was eliminated. Ten years passed between the discovery of the first French AIDS cases in mid-1981 and the virulent press campaign in 1991 when everything fell apart. The subsequent events amounted to more than a "crisis", normally defined by an emergency, organisational overload and short term evolution. The tainted blood scandal ("scandale du sang contaminé") introduced a complicated movement of change extending over several policy areas. The blood transfusion system, the plasma sector and the surveillance system for pharmaceutical

[1]The paper was written in 1998 as part of an international comparison involving twelve advanced industrialized countries : Bayer and Feldman (eds.), *Blood feuds. AIDS, Blood and the Politics of Medical disaster, forthcoming, Oxford University Press.*

products, were all entirely reformed. The previously poorly structured public health sector was upgraded and new institutions set up. Legal responsibilities were clarified in this field and government action extended. Public health dimensions were introduced or reinforced in other policies, notably in the agricultural and food sector, the field of construction materials and environmental issues. A new concept entered public policies: health security ("sécurité sanitaire").

Elimination of the HIV risk in the blood sector was achieved 1985, between 1st August when compulsory screening of blood samples was introduced, and 1st October when heat inactivated clotting factors were provided to all haemophiliacs. In 1992, however, four top executives of the blood transfusion system were sentenced to imprisonment. Neither the penal trial nor the public compensation scheme, which was very generous compared to other countries, calmed the political crisis. On the contrary, they opened the door to further legal procedures characterised by historical precedents and lengthy delays.

The French case of AIDS management provides an example of the complex combination of success and failure in decision-making and governance. General management of the epidemic caused no precise "crisis". Political success went in hand with programme failures, illustrated by permanent conflict within the French agency for AIDS prevention which was finally closed down in 1994, and the high occurrence of HIV and AIDS, three to five times greater than that of Germany and Great-Britain. Public protest was limited to activist circles. An active public policy aiming at solidarity with AIDS carriers was developed during 1988-92 under the second socialist government, with the consensus of the conservatives. All parties had mobilised against the extreme right wing National Front when the it had claimed authoritarian methods and quarantine to be applied to HIV-carriers. *Policy failures were only seen as part of the blood transfusion issue* which attracted all the criticism and passionate outrage.

What was so different between the general issue of the epidemic and the particular blood transfusion issue ? General AIDS management allowed previous public values to be illustrated and reinforced, notably the philosophy of non-exclusion, solidarity and the equal treatment of individuals. Furthermore, therapeutic progress reasserted the role of medical intervention. The contamination of the blood banks, on the contrary, called into question political values and medical benefits. Social confidence in medicine and science was dramatically deceived and a breech in the principle of solidarity with patients was revealed. Risk avoidance in the blood banks called for especially unusual measures in France linked with group targeting and private life: the exclusion of specific groups and places from blood donation, questions on sexual behaviour, compensation for a particular group. *Institutional change was difficult because the required measures*

called into question political and symbolic values ; therefore, the blood crisis reached the top level of the political system .

2. Political arbitration through legal expertise

Management of the blood transfusion crisis proved difficult because of opposing philosophies concerning the damage. The initial orientation shared by many doctors, intellectuals and politicians, viewed contamination through blood transfusion and products as part of the "normal" risk of medical treatment which should not be subject to compensation, unless a specific medical fault was proven. The victims and the press fought for the right to compensation and considered the same facts as irresponsible, as a fault and even a "crime" (poisoning).

The question raised crucial debates within the legal system which finally defined a graded range of reasons for indictment :

- non-assistance to persons in danger, thus underlining the public and professional responsibilities for the prevention of health risks ;
- fraud *(tromperie sur la qualité des produits)*, an indictment which clarified the ambiguous status of blood products. In France, these were traditionally considered as part of the human body, falling under a strict prohibition of commercial profit, but seen as freed from product liability. This problem became an acute issue with the open European market on pharmaceutical products, initially planned for 1989 ;
- manslaughter and involuntary injury, which insisted on the consequences ;
- poisoning, which focused on the conscious choice between different priorities to the detriment of the life of patients.

Legal expertise traced an intermediate alternative between the opposed conceptions. Legal attention centred on negligence and the non-effectiveness of government action. After many different options, the charge against the three ministers was finally qualified as manslaughter. The indictment combined the legal feasibility of a penal trial and the idea that ministers were responsible for government decision- making and for the functioning of their ministries. The debate in the present trial insists on the weakness of active implication: *non*-implementation of official decisions, *non*-information, *non*-assistance, *non*-heating and *non*-importation of virus-inactivated clotting factors.

The legal work changed from pinpointing the haemophiliac issue, in the first trial, to a general view of the blood transfusion system. Investigation extended progressively over the methods of blood collection, the massive collection of blood from places of risk, such as prisons, and over decision-making at government level as well as in sectoral

networks and institutions. Thus the problem seemed to move from the contamination of haemophiliacs as seen in many countries to specific French problems and failures.

Debate in the ongoing trial of the ministers centred on the question of whether governmental action for risk elimination, especially the introduction of blood screening, was rapid enough as stated by several witnesses, or whether it was far too slow as stated in the accusation act. *The general question addressed here is whether normal decision-making and implementation procedures were adapted to this special case*.

The legal procedure progressed in three steps: a first trial of four top executives of the transfusion and plasma sector; a second trial of the ministers; a third procedure, still pending, concerning the professionals, experts and advisers. The question of whether blood security is a "scientific", a "technical" or a "political" responsibility, and whether certain decisions should have been taken by medical experts or the health administration recurs everywhere. The lack of consensus on the nature of the responsibility is at present illustrated by the contradictory position of the General Prosecutor in the ministers' trial who twice concluded in his official reports (1997, 1998), that charges against the ministers ought to be dropped. In the ongoing trial, the problem is approached via the question of *whether or not they had been sufficiently informed*.

3. The "uncertainties" of the early period

Naturally, risk perception has changed since 1984-85, the main problem in France however has been divergence over the gravity and the nature of the risk. The authorities in charge and the measures needed depended on the answers to a question which was never formulated i.e. *who was at risk and to what extent*.

In the mid-eighties, the gravity of HIV-infection was underestimated in France. Only 10% of HIV-positive people were believed to develop AIDS. Minimisation of the risk was favoured by the lack of interest the medical elite showed in the epidemic and the weak position of public health experts. Further controversy in early days concerned the effectiveness of the technical tools of prevention. The first French antibody tests which were an improvement on the American tests, still showed erroneous results in 6 to 10% of the samples. Opponents to the test, therefore, argued that blood screening was useless and might even be counterproductive for public health. False negative results constituted an evident risk for blood banks while false positive results did not endanger patients. Such cases meant a severe psychological shock for individuals with false results, a problem which caused much concern at the time in intellectual and medical circles, and personally to the Minister of Social Affairs. The effectiveness of heat treatment was also controversial in France. Haemophilia specialists demanded scientific

proof that it was 100% effective, in clinical treatment as well as for virus elimination. General risk minimisation culminated in the requirement of absolute effectiveness for the prevention techniques.

The controversy around the initial "uncertainties" related to the acceptable level of risk and for whom, a question which was never formulated in clear terms.

4. The acceptability of the preventive measures

The public health department of the ministry officially called for donor selection in June 1983, but it was not implemented. This elementary precaution met with cultural and professional resistance, rooted in the history of the blood system, institutional practice, professional paradigms and social attitudes towards blood donation.

The importation of heat treated products was excluded because of an unwritten policy of national self-sufficiency, founded on the belief that domestic provision was the safest because it was exclusively based on unpaid donation. Importation was also excluded because of economic protectionism for future European market perspectives. The decision to install a heating process in French production units was taken late and by independent centres. Technical difficulties were encountered in the most important one, the CNTS which provided three quarters of the national consumption.

Reducing the prescription of transfusions in hospitals and clotting concentrates to haemophiliacs was an unlikely option in an access oriented health system. Lack of risk awareness in the medical profession, the doctors' freedom of prescription and little information for patients, meant that such unprecedented proposals where deprived of support.

Tracing systems for transfusion recipients were poorly developed. Patients were rarely informed of the eventual risk of transmission to their families. Medical intervention was seen as an individual act, isolated from its broader consequences.

Systematic screening of blood samples was the *only* method of prevention which could be implemented in the French context of the eighties. Compared to other prevention methods, applied in other countries, France depended totally on screening because it did not call into question previous conceptions, rights and practices. This explains the central importance of "the delay in screening" in the legal procedures, in particular the charge of being guilty of delaying action despite the fact that France was among the first countries to implement the systematic blood screening. Furthermore, as no other free testing facilities were provided at that time, people at risk used the blood banks to obtain

information on their serological situation so reintroducing a risk factor. In tact, the efficiency of blood screening depended on its isolated implementation or its integration in a comprehensive AIDS policy.

The change in problem perception is linked to a *learning process concerning the entire public health system.* It is now accepted that the "one best way" was only one among many others. It was the easiest solution in the specific French context.

5. Public health decision-making.

Delays in donor screening occurred for two "economic" reasons: an attempt to preserve the domestic market for the French Diagnostic-Pasteur and lengthy negotiations on the financing of the proposed measure. The period 1984-85 coincided with reforms in hospital management and the introduction of budget ceilings. Closer examination of the "economic" negotiations, however, revealed typical governance problems which explained why the screening question had to be settled by the Prime Minister himself.

Official investigation revealed the great autonomy of the permanent advisers of ministers in the management of the HIV/blood crisis. The *cabinets ministériels* and their importance in the functioning of government are a French particularity in an international comparison. Even inter-ministerial negotiations are often in their hands. During the eighties, these advisers increased to unprecedented numbers. *(Pouvoir,* 1994, 68).

The ministry in charge of health had little autonomy. The State Secretary for Health was placed under the Minister of Social Affairs for all financial aspects of his decisions. He did not participate in the weekly meetings of all ministers. The Minister of Social Affairs, who was personally suspicious of medical influence[2], had a *cabinet* which counted no medical doctor in its ranks. In this context, it is not surprising that the relationship between the two respective *cabinets* and the circuits of mutual information were described as "bad". Furthermore, the weak public health administration depended for information and advice on the specialist commissions in the blood and plasma sector. The official control functions of the health ministry were in fact in the hands of the institutions and experts of the blood sector.

The presiding judge (*le président du tribunal*) in the ministers' trial recently summarised the evidence with the statement that "the structure of government was ill-adapted to

[2]She attempted to launch an official promotion of the so-called "*médecines parallèles*" (such as acupuncture, natural medicines).

public health decisions". Undoubtedly, Governments reproduce unconsciously the range of values in the society .

For discussion :

- When failure in programme governance *mobilises organised groups,* then initial political success is reinterpreted as failure and may even lead to "scandal".
- Conversely, success in programme decision-making (the case of early blood screening in France) may subsequently be considered as failure because the crisis is reviewed in the light of its *general* context or wider consequences in other policy sectors.
- The same measures, adapted in similar and even identical crises, produce success or failure according to the *national* context, because of different path dependencies, professional attitudes, legal systems and cultural elements.
- The *acceptability of the measures proposed,* in the different constituencies they address, is an essential element in determining the success or failure of programme as well as of political governance.

PART II
Medicine, Justice and the State

The early years of the AIDS epidemic coincided in France with significant social, economic, and political change. But despite living in such turbulent times, the French continued to share a unanimous conviction: their national blood transfusion system was, without doubt, the world's finest example of scientific achievement and social solidarity. The public was thus dumbfounded when the *scandale du sang contaminé* (the contaminated blood scandal) erupted in the early nineties. The fact that half of all French haemophiliacs were infected with HIV and that France accounted for close to 60% of all recorded cases of post-transfusion AIDS in the European Union[3] was surely the result of corruption, dirty money, bad blood, doctors who murdered, state secrets, and conspiracy. These were the elements of the massive press campaign focused on tracking down the guilty parties.

In a television program watched by millions, Georgina Dufoix, one of three cabinet ministers accused by the press as accountable for the catastrophe, pleaded, "*responsable*

[3] On March 31, 1995, France accounted for 56.2% of the recorded cases of the European Union. Data from the European Centre for the Epidemiological Monitoring of AIDS, Paris.

mais non coupable,"[4] responsible but not guilty. The perceptions of 1991 were not the understandings of the mid-1980s, she declared. Dufoix sharply criticised the press, which, she asserted, had sensationalised and exploited a problem of extreme gravity involving extensive human suffering.

The former minister's words roiled the waters. The *Association Française des Hémophiles* (AFH) declared its dismay, the *Association des Polytransfusés* accused the former minister of "discrediting journalists," and the opposition political parties called for changes to be brought "at the highest political level"[5] against the Minister of Social Affairs and against Laurent Fabius and Edmond Hervé, Prime Minister and Secretary of Health, respectively, in 1985. By mid-1990s, former executives of the blood system would be sentenced to prison, and 32 blood sector experts, ministerial advisers, and others who had held the highest political offices would be subject to investigation pending prosecution.

Why were the waves of the "blood scandal" deeper and more violent in France than in other European countries, where the contamination rate of haemophiliacs is similar or even higher ?[6] The story of contamination raises questions of a special kind in France given the hierarchical structure of its public administration and the strong powers of the Executive, which endows national decision makers with a high degree of authority. Why did the French political system not deploy its resources and mechanisms to avoid or limit contamination ? If national expertise and problem-solving capacities proved insufficient, why did France not turn to foreign examples and international learning ?[7].

The lethargy of the French administrative response and the sense of shock reflected in public opinion are linked in a way that reveals the profound significance of blood and the special status of the blood transfusion system. Involved was something more than a public health accident involving medical services. It was not solely the special nature of blood that made swift intervention so difficult and that provoked the paroxysms of outrage when that failure became known. Particular features of the organisation of the French blood transfusion system and its legal[8] and policy-making systems contributed to what came to considered a national calamity.

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[4] TV interview TF1, 3rd November 1991; *Le Monde*, 5th November 1991.

[5] Declaration by the conservative UDF, *Le Monde*, 5th November 1991.

[6] *Quarterly Report*, No. 36, December 1992, European Centre for the Epidemiological Monitoring of AIDS, Paris.

[7] Marie-Angèle Hermitte, *Le sang et le droit. Essai sur la transfusion sanguine*, (Paris: Editions du Seuil, 1996). In this excellent historical and legal analysis of the French blood transfusion system, Hermitte highlights the amazing, virtually total ignorance of those running the French blood transfusion system as to foreign cases and the debates and solutions in other countries.

[8] Doris Marie Provine, "Courts and the Political Process in France," *Courts, Law and Politics in Comparative Perspective,* ed. Jacob, Blankenburg, Kritzer, Provine, Sanders (New Haven: Yale University Press, 1996), pp 177-248.

The Roots of HIV-Contaminated Blood

Background

The AIDS years coincided in France with unusually frequent elections and political change. The rise of the Socialists in 1981 led to political "cohabitation," first during 19986-88 and then again in 1993-95 between a Socialist president and a right-wing parliament - something unprecedented in French History. The Communist Party, associated with the first left-wing government, lost its influence, and a new extreme right-wing party, the National Front, gained a substantial number of votes. This led to growing electoral competition between conservatives and Socialists, which has dominated political life ever since.

The political contest was to influence the HIV/blood story in three ways. First, forthcoming elections delayed decision making. Second, political alternation favoured the growth of "ministerial cabinets," increasing the number of personal counsellors surrounding new ministers. These "shadows of the ministers" had no specific status, but their influence, albeit tacit, was considerable[9]. They filtered access to the minister and information submitted to him or her, prepared files and decisions, gave orders to top civil servants, and co-operated with the cabinets of other ministries. Neither politically accountable to the president of the Republic, as are ministers, nor professionally accountable to administrative jurisdiction, as are civil servants, they were answerable to no authority.

Third, the electoral climate helped to politicise the AIDS issue via the *Front National* (the extreme right-wing party), which won its first seats in parliament in the spring of 1986. The National Front's campaign[10] centred on "national decline," in which immigration, delinquency, drug abuse, and AIDS were all considered part and parcel of the same problem. The unanimous and forceful response of the major political parties and opinion leaders was to defend freedom[11] individual rights, and solidarity with AIDS victims against the risk of stigmatisation and segregation. Therefore, AIDS became the ideological battlefield where political values of equality and universalism were to be demonstrated against a threat from the extreme right, thus diverting attention from the public health problem[12] The result was a political and social consensus on minimising the risks of AIDS. Further, during the entire decade, police repression against drug abuse was reinforced under all the governments, both left and right-wing, so as not to leave this politically sensitive field open to the National Front. As a direct result, the

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9 "La mise en examen des cabinets ministériels," *Pouvoir*, 68, Seuil, 1994.

10 The standpoints of the National Front are presented in the book by its medical adviser, Dr. F. Bachelot. See François Bachelot and Pierre Lorane. *Une société au risque du Sida*, (Paris: Editions Albatros, 1988).

11 Pierre Favre, *Sida et Politique, les premiers affrontements* (1981-1987) (Paris: Editions l'Harmattan, 1992).

12 Aquilino Morelle, *La défaite de la sante publique*, (Paris: Editons Flammarion, 1996).

concentration of drug addicts - potential HIV carriers - continually grew in prisons. This, in turn, would have profound, in unanticipated implications for the French blood system.

It was the commitment to universalism in the face of right-wing challenges that led to social and political consensus[13] that barely took account of the specific profile of the epidemic. The refusal to take into consideration the existence of "at-risk groups" (the term was even banned and replaced by "at-risk individual behaviour") would make any effort to take steps to protect the blood supply through the exclusion of classes of at-risk donors extraordinarily difficult[14].

In addition, economic difficulties contributed to shaping the HIV blood story. During 1981-83, the Socialists tried to stimulate economic growth with a program based on national production, the stimulation of domestic consumption, and an increase in social expenditure, reflected in the popular slogan "buy French," which, of course, implied producing French as well. The biomedical industry featured among official priorities, which helps to explain the emphasis in the early 1980s on national self-sufficiency for blood clotting concentrates relied on by haemophiliacs. A radical policy shift - henceforth maintained by all subsequent governments - followed in 1983. It focused on severe restrictions on public spending, primarily in social fields, which led to budget ceilings for public hospitals on which half of the blood transfusion centres depended. These policies also led to power shifts inside the Health Ministry, marginalising even further the already weak General Department of Health (DGS, *Direction Générale de la Santé)*[15] which had central responsibility for the blood supply.

Historical Roots[16]

Until the *scandale du sang contaminé*, the blood transfusion system in France was held in high esteem, enjoying the confidence of both the medical world and public opinion. The HIV/blood conflict signalled a discrepancy between the system's powerful ethical principals and its organisational structures, and brought attention to the negligence of the transfusion sector. Governed by an anachronistic 1952 law, the system lacked a structure that could be adapted to the industrial production of blood-based pharmaceutical products. AIDS arrived in a legal and regulatory vacuum.

The first transfusion centre was created in a Parisian hospital in 1923. At the time, transfusions were carried out from "arm to arm." Those who provided blood were paid

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[13] Alain Ehrenberg, *L'individu incertain* (Paris: Editions Calmann-Lévy, 1995).

[14] Jean-Baptiste Brunet, "Comportement français," *Les Temps modernes,* 567 (October 1993), pp.52-56.

[15] Bruno Jobert, and Monika Steffen, *Les politiques de santé en France et en Allemagne*, Observatoire européen de la protection sociale (Espace Social Européen) (Paris, 1994).

[16] Marie-Angèle Hermitte, *Le sang et le droit. Essai sur la transfusion sanguine* (Paris:Editions du Seuil, 1998).

for their "donations." Private doctors as well as public hospitals developed networks of professional donors who would provide blood on demand. Until the 1950's before national health insurance was fully operational throughout the country, transfusion recipients paid for their treatment.

The principle of voluntary donation is of fairly recent vintage in France. The good volunteer appeared as an outcome of World War II when injured partisans from the Resistance received free blood donated in secret places under the threat of arrest. With enthusiastic mass collections, voluntary blood donation became a widespread social movement as the Liberation army advanced. The legacy of this "*Route du Sang* ,"[17] which followed the Allied armies, was twofold: the decentralisation of the system, initially placed under the authority of the prefects of liberated territories, and the voluntary donor who entered history as a national hero.

After the war, the political forces of the Resistance strove to generalise the war-born innovation into a national public blood service. Protracted and political struggle set them in opposition to the advocates of the private model with professional donors organised into an extensive network with professional associations and collectively defined obligations as to lifestyle, contracts, tariffs, and publicity. In this competition the voluntary donor was presented as a courageous patriot, ready to sacrifice his or her life for the nation, whereas the professional donor was condemned for being a selfish blood seller, taking advantage of others' misfortunes[18] The medical promoters of the voluntary model were actively supported by the Communist Party, its allied trade union, militant Catholics, and all Resistance-linked organisations.

A changing administrative structure and health care system provided an institutional context that all but assured the success of those who pressed for end to the sale of blood. The newly created Social Security scheme and the development of public hospitals left little space for a private blood system, and the decree in 1952 legalised the triumph of the voluntary militants. It proscribed not paid donation but, rather, any commercial profit from the manufacturing and distribution of blood and derived products. A 1958 judgement by the State Council, in a case initiated by the Pharmacists' Council, prohibited the sale in pharmacies of any product derived from human blood. Their distribution was under the authority of medical doctors and was thus reserved centers and hospitals. In the absence of institutional structures that might have made the sale of blood possible, paid donation disappeared. It was, however, only in 1993 that remunerated donation was legally prohibited.

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[17] Hearing of Professor J. Ruffié, Inquiry Commission of the Senat. SENAT, 1992. *Rapport de la Commission d'enquête sur le système transfusionnel français en vue de son éventuelle réforme, créee en vertu d'une résolution adoptée par le Sénat le 17 décembre 1991* (rapporteur: C. Huriet), document No. 406, Paris, p. 34.

[18] Hermitte, *op. Cit.*, p. 96.

A firm belief in its moral virtues bathed voluntary blood donation in a quasi "religious" aura, according to the American observer Jane Kramer[19] It rested on the "dogma of the unassailable morality of the voluntary donor."[20] Because such blood was assumed to be pure, it was difficult to develop donor screening in France. Indeed, when the first hepatitis B test was introduced (HBS antigen) in 1976, donor screening was discontinued, replaced by biological asseys that tested blood samples, not people.

Until 1991, When they moved into the shadows, blood donors retained a fighting spirit, organising into more that 2000 local associations, which together formed a powerful national federation with more than 800,000 active members. Generously subsidised by the blood centres and local authorities, the associations enjoyed considerable political influence at both the local and national levels[21].

A Heterogeneous Sector Without Regulation

Before the 1993 reform, which in the aftermath of the AIDS disaster was to reorganise the entire sector, France had 170 blood centres (CTS) of which 163 were so-called transfusion centres - in other words, an average of at least one per department. The centres were responsible for collecting blood and plasma and for preparing labile products that could be stored for short periods. They supplied hospitals and the seven plasma fractionating centres. The latter prepared stable products (albumin, coagulation concentrates), which they then resold to hospitals and transfusion centres, which, in turn, supplied patients. The so-called regional centres, of which there were about 30, were affiliated with the major university hospitals. No hierarchical relationship existed among the various centres, which were all legally and financially independent. Half of the blood centres were public bodies, and the other half not-for-profit private organisations, depending on their initial set-up and affiliation with hospitals, local authorities, or associations. All, however, functioned in the framework of blood transfusion as a public service.

The *Fondation Nationale de la Transfusion Sanguine* was entrusted with regional and interregional co-ordination of transfusion policies, with the task of advising the Minister of Health and undertaking research, international missions, and certain technical tasks such as keeping a national list of rare blood group donors. Despite the existence of the *Fondation*, the blood system was fundamentally heterogeneous. When in the 1990s the senate commission established to investigate the blood system in the aftermath of the AIDS disaster sought to characterise its essential features, it noted that the missions of

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[19] Jane Kramer, "Bad Blood," *The New Yorker* (11th October 1993), pp. 74-95.

[20] Michel Setbon, *Pouvoirs contre Sida. De la transfusion sanguine au dépistage: décisions et pratiques en France, Grande-Bretagne et Suède"* (Paris: Editions du Seuil, 1993).

[21] *Ibid.*

the blood centres were "confused and ill-defined," constituting a conglomeration in which the only link was blood[22].

Within the Ministry of Health, the General Department of Health (DGS) was formally charged with the responsibility of overseeing the full range of activities involved in the collection and distribution of blood: approving the CTS's and monitoring their activities; controlling the preparation, conservation, and quality of blood products, as well as the conditions under which they were delivered; and fixing the official prices for blood products, which were uniform throughout France.

Given these responsibilities, it is striking that no office within the DGS had the responsibility of executing this mission. Indeed, the range of tasks was merely part of the administrative duties of a single non-medical official. Furthermore, the DGS depended on advisory bodies made up of blood sector specialists - those who came from the very sector the DGS was to oversee. Finally, the existing administrative rules and standards were utterly inadequate to meet the requirements of effective control over blood products and activities[23].

In 1980, just prior to the onset of the AIDS epidemic, the National Health Laboratory (LNS), the Ministry's technical arm, was given responsibility for approving technical procedures and verifying the quality of blood products. These all-important functions were entrusted to two officials. It was the LNS that would be called upon, in 19985, to authorise the marketing of the first HIV antibody test.

The weakness of the supervisory authority and the resulting confusion of roles had two sources. The first involved the "legal vagueness" that surrounded the responsibilities of the various levels of the blood systems[24] The CTS's were looked upon as self-governing bodies because they were directed by doctors who were professionally independent. Officials from the Ministry of Health were never sure of their prerogatives, and they simply recorded sectoral policies. The second source of weakness was linked to general features of French health policy where the Ministry of Health functioned as an "administrative dwarf"[25] and where blood policy in particular provided an example of

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[22] Sénat, *Rapport de la Commisssion d'enquête sur le système transfusionnel français en vue de son éventuelle réforme, créée en vertu d'une résolution adoptée par le Sénat le 17 décembre 1991* (rapporteur: C. Hurriet), document No. 406, Paris (1992), p 34.

[23] IGASS/IGSJ, Joint report of the Inspection Générale des Affaires Sociales and the Inspection Générale des Services Judiciaires, November 1992. *Rapport d'enquête sur les collects de sang en milieu pénitentiaire. Observations suite à la communication du rapport. Réponses de la mission et synthèse de l'enquête. Annexes.* (Report No. IGAS: SA 07 92 199, No. IGSJ: RMT 13 92), Paris.

[24] *Ibid.*, p. 109.

[25] Morelle, *op. cit.*, p. 211.

"republican feudalism"[26] combining the autonomy of local overlords with a public service lacking State authority.

Technical progress confronted the system with issues for which it was ill prepared. Conceiving a coherent policy of investment and technological choices was difficult in the context of a not-for-profit ideology, independent agents and administratively fixed prices. During the 1970s, many of the CTS's produced antihaemophilic drugs (i.e., frozen and lyophilized cryoprecipitates). Factor VIII concentrates were imported until national production was launched in the early 1980s. Although seven centres engaged in the production of factor VIII clotting concentrates, two of them, the *Centre National de Transfusion Sanguine* (CNTS), one of the two constituents of the Fondation Nationale de la Transfusion Sanguine, and the Lille Centre, accounted for nearly 80% of the national production in 1985. National self-sufficiency was attained in 1987[27] By contrast, the production of factor IX concentrates developed by the CNTS as early as 1959, adequately met national requirements from the outset.

The development of plasmapheresis was viewed by the donor associations as a threat to the symbolic value of blood donation[28] Instead of collective donation near the homes or work places of donors - in most instances, a social occasion - plasmaphersis required donors to make individual appointments and to go to the blood centres, which also had to invest in appropriate facilities. The centres and the donors feared that plasmapheresis would undermine the monopoly of voluntary donation. The slow development of plasmapheresis resulted in intensified collection of full blood[29] and, consequently, in the overuse of transfusions in hospitals. So-called "comfort" and "safety" transfusions were common[30] Indeed, only when the tragedy of AIDS in the blood supply emerged would the consequence of such profligacy become clear.

Blood Transfusion and Blood Product Recipients

The French Haemophiliac's Association (AFH) was founded in 1995 by Professor Jaques Soulier, then the director of the CNTS, together with one of his haemophilic patients. A close relationship with doctors remained a permanent feature of the haemophilic associations. The latter lived in symbiosis with the CTSs that accommodated and funded them. The national association was instrumental in fostering the development of regional associations linked to regional blood centres. They in turn fostered the development of local groups. Their initial goals were to structure the milieu,

[26] Hermitte, *op. cit.*, p. 132.
[27] Jean-Pierre Soulier, *Transfusion et Sida, le droit à la vérité* (Paris: Editions Frison-Roche, 1992): p. 90.
[28] Setbon, *op.cit.*, p. 88.
[29] *Ibid.*, p. 85.
[30] Soulier, *op. cit.*, p. 107.

inform haemophiliacs of available treatment, and pressure the authorities for free access to treatment. In the 1970s, the associations served to teach patients home care and self-injection. They informed families about the four specialised boarding schools for haemophilic children, where they were taught to treat themselves and, in the 1980s, to take their own prophylactic drugs. "All young haemophiliacs went to these schools, where they formed networks and learned to live normally." The philosophy of the haemophiliac's autonomy and his right to live normally was formulated in these associations and schools. The perspective was a reflection of the commitment in social policy during the 1970s and early 1980s to promote autonomy and normal lives for all handicapped individuals, the elderly, and the mentally ill[31] Against the image of the crippled haemophilic, the new ethos promoted an athleticism: "All hemophiliacs to the summit of Mont Blanc." National self-sufficiency in clotting concentrates, it was believed, was to make possible the realisation of the commitment to normalisation.

France has about 40 centres specialised in the care of haemophiliacs. According to the AFH, half of all severe haemophiliacs are treated, often from childhood, in the CTS where they feel they are known. In 1971, haemophilia was added to the list of diseases covered 100% by health insurance. Treatment of the first patients with imported factor VIII concentrates started in 1975-76. After several years of observation, the doctors and the AFH promoted the large-scale use of these new products. At its annual congress in May 1980, the AFH called for the production in France of factor VIII concentrates to by-pass the fickleness of the international market and to conform to the principle of voluntary donation. Both the CNTS and the public authorities supported the proposition. In 1982, funds were made available by the ministry and health insurance to convert the CNTS facility located at Ulis for national production, which started in mid-1983 and increased by 60% in 1984[32]. However, the new production unit had no purification capacity; at the very moment that France embarked on a policy of rapid - and badly controlled - manufacture of factor VIII concentrate, AIDS came on the scene.

HIV in the Blood System

At the start of 1983, only 60 haemophiliacs were undergoing prophylactic treatment with factor VIII clotting concentrate,[33] although wide-scale use had been on the policy agenda for two hears. In an editorial in the AFH journal *Hémophile* (November 1982), the president of the association criticised those running the French blood system for not meeting French haemophiliacs' needs and demanded increased imports of concentrate. Professor Soulier, of the AFH and the CNTS, responded in an "Open Letter to

[31] Monika Steffen, and Martine Bungener, "Les politiques médico-sociales en France," *les politiques de santé en France et en Allemagne*, ed. Bruno Jobert, and Monika Steffen, *op. cit.*

[32] See Annexes in Soulier, *op. cit.*

[33] Minutes of the AFH (French Haemophilic Association) General Assembly, June 1983.

Haemophiliacs," which warned against a premature reliance on the new concentrates. The production of these new agents necessitated twice as much plasma, and therefore twice as many donations, as the production of cryoprecipitates. More critically, "mysterious viral diseases could possibly be transmitted by fractions of commercial plasma…"[34] Hence he urged haemophiliacs to revert to traditional local cryoprecipitates and proposed a two-year moratorium on the consumption and production of factor VIII.

Soulier's warning went unheeded. The final motion adopted at the AFH General Assembly in May 1983 stated that "the potential risk due to AIDS objectively evaluated is not likely to modify current prophylactic treatment," that "it is not necessary to interrupt nor to reduce the treatments…. Importation has to continue [and] national production increase." The Health Minister was asked to take steps toward developing a system that would increase the collection of plasma and enhance the prospect of the development of coagulant factors through genetic engineering[35].

At this crucial juncture hepatitis B served as a conceptual model for understanding the threat of AIDS , a disease that still seemed nothing more than a theoretical danger. Unfamiliar with the risk of HIV, haemophiliacs were loath to "step backward." The president of the AFH, fully convinced of the benefits of prophylactic treatment, played an important part in promoting its use. The AFH was thus caught up in a dilemma with no exit[36]. The parents of haemophilic children, in particular, were anxious not to revert to a former life of discomfort and social handicaps. The prescribing doctors and medical counsellors of the association passed on reassuring messages. Outsider were ignored :

> I tried in the early 80s, together with Doctor H, to lower pooled production in France, but we were confronted with a twofold opposition: the haemophilic association, and their doctors. It was like a family, a solid front of opposition. The treating doctors underestimated the risk; they defended their patients, which is of course, understandable. The problem was that none of us was sitting on the *Comité National d'Hémophilie*, composed entirely of renowned specialists in haemophilia. (confidential interview)

Fuelling the resistance to a return to older forms of treatment was a deep suspicion about the motives underlying such a course. "We didn't believe there was a serious risk, but rather that it was a way to cut health expenses…, because a severe haemophilic costs a lot of money every year, and life expectancy is growing. We didn't want to be the ones that were sacrificed to save the health bill".

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[34] *Hémophilie*, February 1983.

[35] Soulier, Annexes 7-1, 7-2, and 8, pp. 184-188.

[36] Danièle Carricaburu, 1993, "L'Association Française des Hémophiles face au danger de contamination par le virus du Sida: stratégie de normalisation de la maladie et définition collective du risque," *Sciences Sociales et Santé*, No, 3-4, October, vol. IX, pp. 55-61.

Where physicians did not embrace the use of factor concentrate, patients ultimately escaped the full brunt of HIV contamination. Thus haemophiliacs treated at the St. Antoine hospital in Paris, the most AIDS-affected area in France, had a far lower contamination level than the national average[37] They were spared because an old doctor, wary of the new "miracle products", continued to use cryoprecipitate.

Screening Donors

The first official step toward AIDS risk reduction in the blood supply was taken with the DGS Circular of June 1983 asking all blood centres to practice donor selection. This ministerial initiative followed by one month that of the CNTS, which had implemented donor screening and confidential self-exclusion in May. The CNTS initiative generated strong protest from the sole existing gay organisation at the time. The *Comité d'Urgence Antirepression Homosexuelle* addressed an open letter to the prime minister denouncing "anti-gay racism and the use of a biological phenomenon for moralising purposes." The headlines in the left-wing daily *Libération* read, "Bad Blood: Gays, Undesirable Blood Group" and condemned the "drift towards discrimination."[38] The sharp reaction occurred despite the fact that the CNTS had taken into account such concerns and had relied upon a questionnaire focused on personal behaviour, not on group membership. Donations were to be always accepted when other persons were present, even if the sample had to be later set aside.

The editors of the ministerial circular were even more cautious. Prior to publication they had submitted the circular to the Consultative Committee for Blood Transfusion, which, fearing that donors might be made to feel uncomfortable, had reluctantly approved it. In the end, the circular asked the blood centres to identify "at-risk individuals by means of a clinical examination." Only by a note given to donors was self-exclusion of those at risk to be practiced.

As was true in the case of the CNTS, caution did not preclude criticism. *Le Matin*, despite being very close to the Socialists in power, characterised the DGS's method as "indiscreet." The very serious *Le Monde* ran a headline, "Health and Private Life" and questioned whether AIDS represented such a serious threat "that for medical reasons it was necessary to inquire into the private lives of blood donors"[39].

Remarkably, the recommendations contained in the circular were seldom applied at a local level. A survey conducted in February 1984, to which only half of the centres

[37] Internal documents, European Centre for the Epidemiological Monitoring of AIDS, Paris.
[38] *Libération*, 16th June 1983.
[39] *Le Monde*, 16th June 1983.

replied, found that half of the respondents had never made any mention in their screening either of AIDS or of sexual orientation. Ninety percent of the CTS's considered their donors to be risk-free, and only nine centres stated that they systematically asked question on "private life"[40]. Only a reminder published in January 1985 pointed out the legal responsibility of the blood centres in case of transmission.

The sensitivities provoked by efforts to screen out those who light pose a risk to the blood supply are highlighted by the reluctance to move swiftly to prohibit donations by prisoners. Blood donation in prisons started in the 1950s, increased in the 1970s, and reached its peak in 1982-84. These two years corresponded to the period in which the French production of factor VIII concentrates developed rapidly. It also coincided with a period of growing repressive measures against drug addicts, resulting in an increase in the number of intravenous drug users in prison. The blood centres' main motives for collecting in prisons were of a practical nature: in a few hours they could harvest large quantities of blood. For the inmates, et was a welcome break in daily monotony and an opportunity they rarely missed. For the prison administration, blood donation was a way of enabling inmates to exercise their civil rights during detention and to participate in the duty of solidarity. Blood donation was considered an act of "social reintegration"[41] . Indeed, at the Ministry of Justice, blood collection in prisons was administratively attached to the Department of Social Reintegration.

When the risk of AIDS became known, the CNTS immediately stopped its collection in prisons, in April 1983, followed by those blood centres that depended on the Parisian Public Hospital administration. Unfortunately, however, these forerunners did not make public their initiative. The Circular of 20th June 1983, on donor screening did not even mention the necessity of avoiding risky collection venues. Indeed, in 1984 the authorised number of blood collections in each prison was increased.

In was only in the spring of 1985 that the full dimensions of the dangers inherent in prison blood collection were clarified. A prison physician reported that 54% of inmate donors belonged to various risk groups[42]. Efforts on the part of the Director General for Health to formally prohibit blood collection in prisons met with resistance within the Health Minister's cabinet because of strong commitments to the ideology of social reintegration. It was only in the latter part of 1985 that prison blood collection dropped to a tenth of its former level following a joint warning issued by the DGS and the prison administration. The ban was not, however, officially declared: the two central administrations simply warned local officials by telephone. The prime minister's office

[40] Joint report IGASS/AGSJ, *op. cit.*, pp. 106-107.
[41] *Ibid,*, p. 18, Annex 83.
[42] *Ibid.*, p. 164, Annex 133, Report of Dr. Espinoza.

and the chancellery preferred not to be involved in decisions on the matter because establishing a link between inmates and AIDS was considered politically undesirable, a potential cause for "social stigmatisation"[43] Blood collection was continued in several prisons until 1989 and only stopped completely in 1991. Blood from prisons accounted for less than half of one percent of the total national supply until 1985, but those donors were responsible for as much as 25% of the cases of contamination through blood[44].

Testing Blood

The advent of testing for blood contamination was made possible by the development of the HIV antibody test, and mandatory screening of donated blood became an urgent demand from transfusion leaders and others concerned with the blood supply at the beginning of 1985. The urgency of the situation was underlined by a profoundly troubling epidemiological memorandum prepared by Dr. Jean-Baptiste Brunet from the DGS. On the basis of AIDS prevalence found in the donors of two Parisian blood centres, Brunet demonstrated that "It is probable that all the products prepared from pools of Parisian donors are currently contaminated"[45]. The official decision to introduce mandatory screening was announced in Parliament by the prime minister, and became applicable on 1st August 1985. France was thus one of the first European countries to institute mandatory screening of blood, yet it is clear that such screening could have been instituted three months earlier. Documents now available as a result of official inquiries reveal the play of interests and concerns that delayed such testing.

First, the French authorities sought to protect the French market from an invasion by American HIV antibody test kits produced by Abbott. The latter had filed an application, on 11th February 1985, for authorisation from the National Health Laboratory (LNS) to market the test, at a time when the French firm Diagnostics-Pasteur was not yet ready to face international competition in its own domestic market. Its initial price was almost twice as high as Abbott's. Abbott's marketing license was therefore delayed. The second problem concerned the financing of blood screening, which necessitated lengthy negotiations with the Social Security Department before the latter would agree to the integration of such costs into the official prices for blood products, for which health insurance would have to foot the bill. Third, a small group of AIDS specialists, notably Dr. Brunet, stressed the necessity of providing free and anonymous testing facilities *before* blood screening was introduced, to avoid a situation in which at-risk persons might donate in order to determine their own antibody status. Finally, there were ethical concerns about what precisely would be told to those who tested positive,

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[43] *Ibid.*, p. 176.
[44] *Ibid.*, pp. 62-63.
[45] Dr. Jean-Baptiste Brunet, Mémorandum of March 12, 1985, DGS, Health Ministry.

given the uncertainty of the clinical significance of this finding[46]. Indeed, some argued that given the risk of discrimination and the psychological burden of being informed about a potentially inaccurate or uninterpretable test result, individuals should not be notified of the results of donor testing.

These issues were discussed at an inter-ministerial meeting called by the prime minister's main adviser on 9th May 1985. The decision was taken to postpone approval of the American Abbott test in order to provide Diagnostics-Pasteur with time to enhance its own prospects. Central to that decision was the influence of those who sought to give priority to financial and industrial considerations over those that touched on matters of public health. After the meeting, the prime minister's and the health minister's chief advisers agreed that despite the importance of protecting French industrial interests, the early introduction of screening could be politically advantageous in a pre-electoral period. France's image abroad would be enhanced; the press and physicians would be satisfied.[47] Thus, just two days after the prime minister's announcement in Parliament that France would require testing of blood donation, on 1st August 1985, the Pasteur test was given its marketing license. A month later, the Abbott test was licensed.

Remarkably, the prime minister himself made the formal determination[48]- based on the advice of both ethical and medical authorities - that those who tested positive would have to be informed of their antibody status. Finally, on the question of whether testing of blood donations could commence in the absence of venues where those who wanted to know if they carried antibody to HIV could be tested, the advice of AIDS experts was ignored. Such anonymous and free test sites did not open in France until 1987, although health insurance coverage for antibody tests ordered by physicians was available in February 1987.

Viral Inactivation of Factor Concentrate

When the blood scandal broke in France, a central element of the controversy was the question of when viral inactivation of clotting factor could have been instituted. Like so much else surrounding blood, involved was a mix of scientific uncertainty, dogma regarding the risk-free nature of volunteered blood, and national industrial policy.

Although the CNTS had begun to explore the possibility of viral inactivation in 1983, the leadership of the fractionation centre at Lille only came to appreciate the

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[46] Comité Consultatif National d'Ethique pour les Science de la Vie et de la Santé, *Rapport concernant les problème éthiques posés par l'appréciation des risques du Sida par la recherche d'anticorps specifiques chez les donneurs de sang*, Paris, 13th May 1985.

[47] Morelle, *op. cit.*, pp. 80-81.

[48] Michel Lucas, 1991, *Transfusion sanguine et Sida en 1985. Chronologie des faits et décisions pour ce qui concerne les hémophiles*, Report by the head of the IGASS inspection board (Inspection Générale des Affaires Sociales) (Paris, September, 1991), p. 42.

urgency of the matter in mid-July 1984. But even in late 1984, the president of the French Haemophilia Foundation still expressed uncertainty about the benefits of heat treatment. Writing in *Hémophile*, he stated that although the data on such processing was "interesting" it was crucial to "wait for the results of experiments being conducted by French experts"[49]. In the interim, haemophiliacs should "trust their experts and doctors and the products they prescrib[ed] to us." When Jean-Baptiste Brunet informed a November 1984 meeting of the Consultative Committee that both French and international studies were conclusive regarding the efficacy of heat treatment, an eminent expert on the treatment of haemophilia replied that this "still needed to be proved"[50] As late as March 1985, a specialist writing in Hémophile could assert that it was only a matter of "intellectual deduction" that heat treatment could inactivate HIV, for the process had been designed to confront the challenge of hepatitis B. Other, *French*, studies were needed. As the Lucas report[51] was later to show, treatment specialists were doubtful about the reliability of foreign studies.

By the spring of 1985, doubts began to vanish and pressure from haemophiliacs for large-scale importation of heated products began to mount. Brunet had prepared a memorandum stating that "all batches of [concentrate] produced by the CNTS were probably contaminated" with HIV. But such alarming epidemiological data at hand, France was utterly unprepared to provide inactivated concentrate. In April, Lille was just testing its heating process. In June the CNTS attempt at heat treatment failed for technical reasons.

Given the urgency of the matter, the CNTS could have undertaken the massive importation of inactivated concentrate. That, however, would have meant the failure of national industrial policy entrusted to it by the public authorities. As a consequence the CNTS chose to embrace an ultimately disastrous "transition period" during which untreated concentrates would still be distributed. In the absence of a clear understanding of the potentially dire implications of delay, the Haemophilia Association declared that only as of 1st October, should the distribution of untreated factor concentrate be prohibited, even if that necessitated massive importation[52].

Despite the fact that officials responsible for the distribution of factor concentrate knew that "the probability of not having contaminated batches is very slight"[53] they continued to press for the use of remaining stocks. In June 1985 Dr. Michel Garetta Director of the CNTS, wrote a memorandum urging that the use of untreated factor should remain

[49] *Hémophilie*, Editorial, October, 1984.
[50] Professor Duclos, quoted by Morelle, *op. cit.*, p. 311.
[51] Lucas, *op. cit.*, pp.22-24.
[52] *Hémophile* 102, September 1985.
[53] Lucas, *op. cit.*, Annex 23.

"standard procedure except for specific requests"[54] A CNTS memorandum of August 1985 was sent to two Parisian hospitals asking them to "try to distribute untreated products to HIV-positive haemophiliacs"[55].

The decision to introduce the transition period provoked no more that a single written protest, addressed on 5th July to the president of the National Blood Transfusion Society. The concerned physician referred to his professional conscience in asking for the immediate prohibition of unheated products. The letter was circulated throughout the many national commissions and organisations until the end of November, when officials concerned with haemophilia treatment policy stated that it was no longer relevant.

Two DGS decrees, both issued on 23rd July 1985, closed the affair. One instituted mandatory screening of all blood donations on 1st August; the other declared that unheated products would no longer be paid for by the health insurance as of 1st October, amounting to a prohibition. The CNTS started heated production in mid-September 1985. At the same time, a circular from the DGS made viral inactivation compulsory for all production centres.

But even then untreated stocks in patients' homes, in hospitals, and CTS's were not recalled. Only the treatment centre in the city of Rouen recalled products from its individual patients[56] An inquiry carried out in 112 blood centres concluded that significant unused stocks still existed on 1st September, amounting to a total of 30 million IU, only part of which were returned to the CNTS for destruction[57].

The policy that covered the transition period was formulated by transfusion leaders, legitimised by advisory bodies, and then endorsed by the DGS. The health minister never intervened. It was during the transition that unsafe concentrate was provided to trusting haemophiliac patients. When illness and death crept up on the close-knit community of haemophiliacs in the following years, notably during 1988-90, they argued that they had agreed to the delays and the transition period only because they had never been made privy to the data made available to officials by Jean-Baptiste Brunet in March 1985.

The Epidemiological Aftermath[58]

[54] *Ibid.*, Annex 28.
[55] *Ibid.*, Annex 29.
[56] *Ibid.*, p. 53.
[57] Soulier, Annex 27, pp. 66, 213.
[58] Data from the Réseau National de Santé Public, Paris.

Epidemiological factors, clinical practices, and the process of policy making contributed the iatrogenic disaster of blood-borne AIDS in France. As of December 1996, 1743 cases of AIDS, including 89 paediatric cases, were reported as a result of transfusions. Two thirds of the patients have died. Five hundred and forty-three haemophiliacs, including 51 children, of a total haemophiliac population of 5000 had developed AIDS because of contaminated clotting factor. One hundred and eighty-seven heterosexual cases of AIDS were linked to the blood-borne HIV infection of sexual partners.

HIV infection is, of course, more widespread. It is estimated that between four and six thousand cases of infection occurred because of transfusions or the use of blood products. More than 1200 haemophiliacs - 40% of the 3000 people with severe haemophilia - were infected.

Nevertheless, a comparison of regional data clearly shows that the general prevalence of AIDS is the basic factor behind blood-related AIDS prevalence - regions with the highest prevalence of AIDS have the highest number of transfusion-related AIDS cases. Thus the Parisian region (Ile-de-France), the Marseilles and Côte-d'Azur region, and the French West Indies (Antilles-Guyane) with the highest rate of AIDS cases per million population (1,801.8) had an AIDS case rate from blood transfusion and products of 69.4 per million population. In the regions with the lowest AIDS prevalence, blood-related contamination is also far lower (Franche-Comté, l'Alsace, Nord Pas de Calais). In Franche-Comté, with en overall case rate of 210.1 per million, the case rate from blood was 12.8.

While geography was destiny for blood transfusion recipients, the picture was more complex for haemophiliacs, whose rates of infection varied according to the policies of the transfusion centres and the prescribing practices of doctors. The relative protection afforded by a low AIDS prevalence of by donor screening - when effectively implemented - was neutralised by the technique of pooling thousands of donations. Thus the sad case of Aquitaine, which holds the record for AIDS prevalence related to the blood system with 74.4 cases per million population. The Bordeaux blood transfusion centre - the supplier of drugs to haemophiliacs in the region - had relied on the largest prison in the region for blood. At the other extreme we find the Nord-Pas de Calais region (case rate 9.1), which combines the lowest AIDS prevalence in the country with the fact that the regional transfusion centre at Lille was the first in France to introduce a heating technique, in the spring of 1985.

Mobilisation, Public Action, and Litigation

One night in 1989, Dr. Michel Garretta, who was then engaged in negotiations with the European Community concerning the forthcoming open market for blood products, discovered that his car was burnt in protest. The following year he was decorated with the *Ordre National du Mérite*, on the request of the president of the Republic, despite the reservations of the health minister, who was already involved in ongoing negotiations over the question of compensating haemophiliacs infected with HIV. The turn of the decade marked a watershed; what demands had been made in prior years because of HIV in the blood supply would pale when compared to the explosion of outrage that would ensue. The number of recorded cases of full-flown AIDS related to blood treatment has shot up in 1988-89, and the perception of the problem changed. Victims of blood-borne AIDS transformed themselves into a vital political force.

Victims Without Voice

The emergence of effective, organised protest on the part of haemophiliacs had to overcome a number of obstacles rooted in the nature of the blood collection system, the relationship of haemophiliacs to their physicians, and the legal regime surrounding blood. But as protest emerged it met with opposition from vested interests. Voluntary blood donors tolerated no criticism on blood issues and acted as powerful spokespersons for the blood centres. When in a May 1986 television interview several haemophiliacs expressed doubt regarding French products, the president of the Blood Donors' Association wrote to the AFH president to protest. "The CTS cannot accept unwarranted attacks on the quality of their blood. Voluntary blood donors have never asked for the slightest thanks from those who benefit fully from their generosity. There is no reason why they should stand for insults from them. Haemophiliacs' total dependence on the donors' voluntary, free gesture make their attitudes unjust and almost odious"[59].

The AFH had no allies. In part, this isolation was self-imposed. Haemophiliacs refused contact with the newly created associations for the defence of people with AIDS, whom they considered responsible for the blood contamination. The opposition by gay men and professionals caring for drug addicts to the screening of blood donors and even of blood samples reinforced this argument. Furthermore, the AFH wanted to remain outside the social mobilisation around AIDS in order to avoid any association between haemophilia and the stigmatised epidemic. "We invited the editors-in-chief of the newspaper to explain our situation and ask them not to talk about us. You see, haemophiliacs are always boys. We didn't want to be linked to homosexuality. It's not so long ago that we were a stigmatised people." (interview) The newspapers complied with the request until 1990.

[59] Letter and further documents reproduced by Anne-Marie Casteret, *L'affaire du sang* (Paris: Editions La découverte, 1992), pp. 196-209.

Initially, haemophiliacs hid their HIV-positive status for fear of losing their jobs or, in the case of children, not being accepted in school. It was in the struggle for compensation that haemophiliacs shed their accommodationist political strategy.

Legal and political dispute erupted when a minority of dissenters, who criticised the Haemophilia Association's low-profile strategy focused on behind-the -scenes negotiations, broke with the AFH. Jean Garvanoff, an atypical haemophiliac who had not been part of the "community" of patients and caregivers, sought to make the haemophiliac problem public, to mobilise the press and political parties, including the National Front, which seized the case as an opportunity to criticise the political establishment.

From 1986, when the non-socialist parties returned to power, the AFH had tried to obtain aid from the Minister of Health, who refused "to pay for the socialists' mistakes." (interview) If there was governmental or medical responsibility, haemophiliacs would have to take the matter court. The minister, however, set up a commission to study medical and social benefits for haemophiliacs with AIDS. Following recommendations put forward in May 1988, the minister subsidised the Haemophilia Association so that it could pay a social worker to assist families with financial difficulties. Despite growing internal contentiousness, the Association was to adhere to its choice for a collective, united approach: "There was terrible internal friction with those who wanted legal action, even violent action, including against the AFH leaders - I personally received written threats - but we thought that in legal action only a part of the haemophiliacs would be able to supply proof - proof of dates, of the doctor's fault, etc. - and obtain compensation. We opted for solidarity between all of us, so that *everyone* might obtain something." (interview)

Several activists broke away from the AFH and filed claims in the courts. The first such moves occurred in March 1988 against the CNTS for the misdemeanour of merchandising fraud. A second series followed in April, broadening the affair to include the National Health Laboratory, the National Ethics Council, and Even the AFH, all on the grounds of manslaughter and non-assistance to persons in danger. In April, 1989, Jean Garvanoff, together with his brother - also a haemophiliac - and the other dissidents, founded a second association, the *Association des Polytransfusés* , as an alternative to the AFH.. The new association filed a third series of claims against both the CNTS and the AFH for fraud and non-assistance to those in danger.

1991: The Year Things Fell Apart

The flames of discontent were fanned by the media. Anne-Marie Casteret, a journalist at the weekly *L'Evénement du Jeudi*, undertook her own inquiry, which in 1992 would

appear as a book, *L'affaire du Sang*. In April 1991 her magazine published the minutes of the internal CNTS meeting at which the continued distribution of factor VIII concentrates, known to be contaminated, was planned. This news sparked off a vehement press campaign that was to so define the French experience. Other newspapers started their own investigations and, day by day, the public, astounded and avid for further revelations, discovered new documents stamped "confidential."

The blood scandal that emerged in 1991 was shaped by a veritable press war that provided the foundations for a new kind of medical journalism[60]. *Le Monde*, with its long-standing tradition of medical journalism, was locked in conflict with less established journalists trying to assert themselves. While the former adopted a posture emphasising the "medical disaster" and collective errors, the insurgent journalists pinpointed the decisions made by individuals underlining both their mistakes and malicious acts. The press grasped the opportunity to modify its relations with politicians, the medical profession, and the legal world - three areas of society in which the French press had relatively little autonomy. The affair provided an opportunity for young journalists to assert themselves in a highly competitive professional sphere, as medical journalism shifted from the hands of doctors to those of journalists wanting to specialise in medical issues. The blood affair also encouraged investigative journalism, a relatively undeveloped field in France.

While the Minister of Health remained silent, transfusion officials and journalists confronted one another on TV and in the medical press. The former argued that without the distribution of at-risk concentrates, haemophiliacs would have died from loss of blood. They claimed that there had no been enough heated products at the time on the market, and that the problem had been similar in other countries. Based on new documents, which they discovered, journalists denounced "the monopoly" that prohibited doctors from prescribing inactivated drugs produce abroad[61]. A cabal among the state, doctors, and Dr. Garretta had betrayed the interests of haemophiliacs.

Dr. Garretta resigned on 3rd June 1991, considering himself the victim of "an aggressive and partial press campaign of orchestrated misinformation"[62]. In the ensuing months the press made public what seemed to be a picture of sordid financial relations within the blood sector. For the press, the contaminated blood affair has become a question of dirty money.

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[60] Patrick Champagne, in collaboration with Dominique Marchetti, "L'information médicale sous contrainte A propos du 'scandale du sang contaminé,'" *Actes de la recherche en sciences sociales* 101-102 (March 1994): 40-62.
[61] Anne-Marie Casteret, *L'affaire du sang* (Paris: Editions La Découverte, 1992), pp. 196-209.
[62] *Ibid.*, p. 233.

In September 1991 the report by the General Inspectorate for Social Affairs was issued. Known as the Lucas Report, it established an official chronology of events and decisions and pointed out the incoherence within the decision making system. The Lucas Report also provided an important document that journalists had sought in vain, the minutes of the inter-ministerial meeting in May 1985 in which it was decided to delay introducing the AIDS blood test in order to give Pasteur-Diagnostics a better chance in the marketplace. The press was henceforth to turn its attention to those "responsible in the ministries"[63] The scandal turned political. It was in this context that criminal charges were brought against four leaders in the field of blood transfusion and public health. It was also in this context that François Mitterand, president of the Republic, entered the fray.

On 10th November 1991, the president of the Republic announced during a televised speech that "we need a law, we need parliament as a whole to be involved in the measures that have to be taken to compensate [for] damages which can never be entirely compensated." Legislation - the law of 31st December 1991 - establishing a public indemnification plan was unanimously approved by parliament.

Whatever its shortcomings, such as the tendency to mischaracterize technical issues raised by the blood scandal, the press had effectively drawn attention to the victims of tainted blood and had mobilised public opinion. In so doing it had forced the government to act.

The Long Road to Compensation

The political system of the Fifth Republic, which provides wide autonomy to the executive, affords limited capacity for initiative in the French parliament. Unlike the National Assembly, however, the Senate can define its own agenda. The struggle for compensation began in 1987, when the Social Commission, in a conservative Assembly, drew up a report proposing a compensation scheme for HIV blood victims that was never put on the agenda[64] Transfusion recipients, who were not at all organised, later found a highly effective spokesman in a senator who had a family member infected by a blood transfusion. He mobilised interest in transfusion-associated AIDS within the Senate and helped to found an association to defend the interests of transfusion recipient victims, the *Association de Défense des Transfusés*. The senate tabled a bill in 1990 and suggested public compensation far all victims contaminated before 31st December 1986.

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63 *Ibid*., p. 237.

64 Monika Steffen, *The fight against AIDS. An international public policy comparison between four European countries (France, Great Britain, Germany, Italy).* (Grenoble: Presses Universitaires de Grenoble, 1996).

The return of the Socialists to power in 1988 opened the way to a collective compensation scheme, albeit under pressure. Negotiations for the first compensation scheme were held together with the insurance companies, without consulting the AFH. "The health minister's cabinet telephoned us, saying they were preparing a plan for us and asking a few technical details. We were never asked to give our views on it. Afterwards we were simply informed of the result, the mixed fund, and the amount of money given to it." (interview)

This first compensation scheme was limited to haemophiliacs. It was presented by the government as an exceptional case and as an act of "solidarity," as opposed to a "reparation for injury" in the legal sense of the term. In July 1989 a protocol agreement, known as the "Even Agreement" after the Minister of Health, was signed by four parties: the insurance companies, the AFH, the transfusion institutions, and the state. It provided for payment by the insurance companies of a fixed sum of 100,000 FF (US$ 20,000) to each HIV-positive haemophiliac. The state was to indemnify acute AIDS cases, with payments depending on age and family situation but not exceeding 620,000 FF (US$ 120,000). A widow would receive 170,000 FF with 40,000 FF for each child (US$ 34,000 and US$ 8,000 respectively). The insurance companies, following convention, demanded that each beneficiary give up the right to institute further legal proceedings. The minister's advisers, on the other hand, insisted that the state's compensation fund should not be bound to the renunciation of further legal proceedings. While most haemophiliacs accepted the plan, the wealthier did not. Once again, the cohesion of the haemophiliac community was threatened. The *Association des Polytrasfusés* sharply criticised the scheme. So too did the press and the opposition parties. Public opinion was also unfavourable. At the centre of the criticism was the antagonism to the reliance, at least in part, on private financing.

Implementation of the controversial compensation scheme was lengthy. As a result, in 1990 the AFH embarked on a strategy of political mobilisation for a new compensation law. Thus a scheme designed to diffuse the conflict became the occasion for further protest. The regional and local sections of the AFH actively lobbied with letters and petitions addressed to all deputies, senators, and local politicians. At the same time, the senate and the new association of transfusion recipients pushed for a general compensation law for *all* victims. The law for victims of terrorism, which had been passed in 1990, became the common reference for all parties concerned.

For both medical and legal experts, a central concern raised by the issue of compensation entailed the problem of who should bear the burden of proof and how such determinations would effect the concept of responsibility for medical errors. If the onus remained on victims to prove the precise nature of the medical fault, most would

find the path to compensation all but foreclosed. However, if no showing of fault was necessary, doctors and medical institutions would be permitted to escape professional liability[65] Neither seemed acceptable. And so, ultimately, a consensus was reached that sought to preserve the advantages of a no-fault system with those of a liability-based approach. Victims were to be freed from the burden of legal proof, but in cases where evidence existed of specific acts leading to infection with HIV, legal procedures would permit plaintiffs to seek compensation from those who were responsible.

Once the principle of compensation had been accepted, it was necessary to determine the class of eligible beneficiaries. Should only haemophiliacs be covered, or should transfusion recipients be covered as well? And if transfusion recipients were covered, why not transplant recipients and those who had become infected through artificial insemination? If those who had suffered from such medical accidents deserved compensation, why not individuals infected through occupational injury ? In the end, all such individuals were deemed eligible. Gay leaders and some allied Parisian intellectuals who opposed the "blood and medically oriented" compensation policy as unjust, asked why the medically infected should be treated differently from others infected with HIV. They found no political support for their argument, though, except from the National AIDS Council (*Conseil National du Sida*). The *Conseil* criticised the "moral distinction" between the "good," "innocent" AIDS victims and the "bad," "guilty" ones. Like the earlier government report[66], the National AIDS Council's perspective derived from a commitment to oppose all forms of discrimination, even the creation of special programs *for* those with AIDS. The government responded to such criticism by emphasising that it was not AIDS itself which was a national calamity justifying compensation and national solidarity but the spread of HIV through the national transfusion system.

The Compensation Fund, established by the 1991 Act, provides compensation for all people infected with HIV through medical treatment or actions, including transfusion patients, their infected partners (for unmarried partners, the question remains open, but these cases are generally accepted), their children, and their heirs. Five years later, in 1996, health care workers infected occupationally would be added to those entitled to the Fund's benefits under the same conditions. The new Fund was state-financed. It received a single endowment of US$ 220 million from insurance companies, the result of negotiations on the previous compensation plan, and a state subsidy renewed annually in accordance with the Fund's needs. The Fund guarantees applicants a swift decision

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[65] Laurence Engel, "Vers une nouvelle approche de la responsabilité. Le droit français face à la dérive américaine," *Esprit,* 6 (June 1993), pp. 5-31.

[66] Claude Got, *Rapport sur le Sida. Rapport au Ministre de la Santé* (Paris: Editions Flammarion, 1988).

on their cases without legal procedures (three months for acceptance of the case, and three months further for calculating the compensation sum fixed by the Fund).

Under the new law, victims have two available paths: they may seek compensation from the Fund without having to present proof of culpability - the presence of HIV infection and of previous blood-related treatment is sufficient; or they may, through litigation, seek to obtain higher compensation - if, for instance they believe a particular act of medical malpractice can be proved. Those who pursue the path of litigation are not barred from seeking compensation from the Fund if they fail in the courts.

The level of compensation from the new Fund is much higher than previously established sums and takes into account damages in the way they would be assessed by a court of law. Emotional distress due to infection, handicap from the illness, loss of years of life, and economic losses for the victims and their heirs are all considered. For a diagnosed AIDS case in an adult man with an average income, compensation may range from the equivalent of US$ 150,000 to US$ 400,000. Compensation for emotional distress and damage to health are calculated according to age, with young people entitled to far more than older people. According to the 1992 and 1993 annual reports of the Compensation Fund, indemnities paid out for economic loss may vary considerably. In that two-year period they ranged from $3,000 to $500,000 per case. Between March 1993 and February 1994, the Fund handled 11,000 cases (4000 involved victims and 7000 family members)[67] Experts estimate the total amount that France will pay out to its HIV blood victims at around 6 to 7 billion French francs (US$ 1.2 to 1.4 billion)[68].

The broad scope of the HIV compensation scheme and its generosity provoked demands for extension of its underlying principle to others. Mounting social pressure for compensation come from victims of other transfused pathologies, notably hepatitis. The AFH strongly supported hepatitis C compensation because many haemophiliacs were affected. Liver specialists also supported the proposal The underlying question was whether compensation should be extended to *all* medical accidents. As these are often linked to transmissible disease or to scientific and technological innovations, it was argued that victims should be freed from the onus of legally proving "medical mistakes." An initial proposal for such broadly based compensation was, in fact, first put forward two years before the passage of the 1991 act, supported by the numerous small associations of medical victims and the last Socialist Health Minister Bernard Kouchner. The latter commissioned a social scientist to examine the question. The

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[67] Fond d'Indemnisation, annnual reports, 1992,1993, *Rapport annuel sur le dispositif d'indemnisation des hémophiles et transfusés: mars 1992 - février 1993; Rapport annuel sur le dispositif d'indemnisation des hémophiles et transfusés : mars 1993- février 1994*, internal reports to the parliament and to the government, Paris

[68] *Le Monde*, 5th November 1994.

resulting Ewald Report, published in October 1992[69], strongly supported the idea of compensation for all victims of iatrogenic injury as a logical step forward for the welfare state. However, the medical profession and the opposition raised strong objections, arguing that it would mean the end of individual responsibility and would be too costly. In an obviously political manoeuvre the government, however, tabled the bill at the end of 1992, and it had no chance of surviving the spring 1993 elections.

Turning to the Courts: Civil Litigation and Criminal Prosecution

Nearly 2000 cases involving transfusion recipients and haemophiliacs have been brought before the courts. The central question posed by these cases is whether the legal standards that govern medical practice or product liability will apply[70] Doctors and hospitals have an *obligation de moyens* (a legal obligation to provide all available care). They can be held liable by patients if they fail to provide treatment that is technically available, or if they are negligent. Producers and suppliers, on the other hand, have an *obligation de résultats*, en obligation to produce expected results. The *Cour de Cassation* relied on a notion of product liability in cases involving medical institutions covered by civil jurisdiction. By contrast, the judgements of the administrative courts dealing with public entities varied[71]. Several of them, as well as the appeals courts, maintained the *obligation de moyens* and demanded proof of negligence. From 1991, administrative courts adopted the notion of product liability. In June of that year the Administrative Court of Marseilles ordered two hospitals to pay a total of FF 600,000 (US$ 120,000) to a transfusion recipient on the basis of hospitals' *obligation de résultats*.

Finally, at the end of 1991, the Administrative Court in Paris ordered the State to pay FF 2 million (US$ 400,00) in damages to a haemophiliac because it had not prohibited the distribution of unheated products after if had been warned by Jean-Baptiste Brunet that virtually all factor concentrate was contaminated with HIV. The court stated that "once information on a public health disaster had been made available, it was the responsibility of the State to withdraw the contaminated or risky products." It also found that mandatory screening of blood donations could have been instituted three months earlier than it was. This judgement, establishing public responsibility, was confirmed twice, by the Administrative Court of Appeal in 1992 and by the *Conseil d'Etat* (9th March 1993).

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[69] François Ewald, *Le problème français des accidents thérapeutiques: enjeux et solutions*, Report to the Minister of Health and Humanitarian Action (September-October 1992) Paris.

[70] Hermitte, *op. cit.*

[71] *Ibid.*, p. 275.

Lawsuits brought by haemophiliacs and those infected through blood transfusions thus began to establish the contours of the responsibility of physicians and medical institutions to those who were in their clinical care. But such suits paled in terms of the high drama associated with the laying of criminal charges against officials responsible for the French blood system. It was the trial of those individuals that would rivet the attention of the French public and that would mark the experience of France as unique among other nations that confronted the iatrogenic tragedy of AIDS and blood.

The criminal inquiry under the investigating judge in Paris lasted for two years and led to charges against four individuals: Dr. Michel Garretta, director of the CNTS; Dr. Jean-Pierre Allain, scientific director of the CNTS and adviser to the Haemophilia Foundation; Professor Jacques Roux, director general of health; and Dr. Robert Netter. The process of coming to an agreement over the precise nature of the charges to be levelled was characterised by extended controversy that occupied legal specialists and filled the press. In the end, two options remained: fraud regarding the quality of blood products sold, classified as an "offence" (*délit*); and poisoning, defined as the administration of a harmful substance *known* to lead to death, and classified as a "crime." The implications of a finding of guilt for an offence, as contrasted with a crime, were stark. In the case of fraud, the maximum penalty was four years imprisonment. Poisoning could incur a life sentence.

Jurists and especially the victims' lawyers were divided over the appropriate charges to be brought. Involved was not just the question of the potential severity of the punishment but the pragmatic matter of which charges would be most likely to elicit a guilty verdict. Each camp wrote a book defending its standpoint[72]. Both parties solicited the opinions of eminent professors of law, which led to a stormy academic debate on the legal meaning of "poisoning." The urgency of coming to a resolution of this conflict compelled the parties to reach some practical agreement. The investigating judge, the public prosecutor, most of the victim's lawyers, and the government agreed to limit the charges to "offences": fraud and non-assistance to persons in danger. Although criticised for being no more than a *délit d'épicier* (a minor misdemeanour), fraud was chosen in order to satisfy both the victims and public opinion. The choice of a "minor offence" ensured that the trial would indeed take place and that guilty verdicts with punishments would follow. Had the indictment been for poisoning, there was concern that a popular jury would balk at finding doctors guilty[73].

[72] For the two points of view, see Sabine Paugam, *Un sang impur. L'affaire des hémophiles contaminés* (Paris: Editions JC Lattès, 1992); Caroline Bettati, *Responsables et coupables. Une affaire de sang* (Paris: Edition du Seuil, 1993).

[73] Paugam, *op. cit.*, p. 89.

The public prosecutor thus charged the defendants with having failed to take steps that might have protected haemophiliacs and blood transfusion recipients[74]. Dr. Garretta was accused of having "lied and manipulated" in order to protect the industrial interests of the CNTS. Dr. Allain was said to be guilty of duplicity in defending Dr. Garretta's decisions on heat treatment even though he privately found them mistaken. The director general of health, Professor Roux was allegedly accountable for having failed to stop the distribution of unheated clotting concentrates, although he could have done so by ministerial decree. Dr. Netter, asserted the prosecutor, could have authorised the marketing of the Abbott HIV antibody test kit but had yielded to those who insisted that the French-produced Pasteur kits be given priority. Finally, both Drs. Roux and Netter had been guilty, charged the prosecutor, of a dereliction of duty in not having warned the minister of health of the gravity of the situation. It was the failure of Netter and Roux - two senior civil servants - that implicated the state in this catastrophe.

The trial opened on 22nd June 1992, in a tense, tiny courtroom[75] Pressure from haemophiliacs wanting to attend was so great that the trial was moved to a larger venue. Public authorities, fearing an attack against the accused - by means of a syringe containing a victim's contaminated blood - decided that the public would have to be searched at the entrance. On the first day of the trial, such searches did occur. But Dr. Allain opposed such measures and threatened not to participate in his own trial if the searches continued. Allain prevailed, and these security measures were halted. In the courtroom one could hear members of ACT-UP chanting slogans against the state and doctors. The trial was headline news for four months.

Testimony by the prime minister, the minister of social affairs, and the minister of health was heard on 24th July, one month into the trial[76]. Each of them - and notably the prime minister - bowed before the pain of the victims. This gesture caused murmurs and protests among the haemophiliacs, while the ACT-UP slogan, "AIDS - The politicians knew - They murdered" could be heard from the street. The eagerly awaited hearing was disappointing. All three former ministers claimed not to have been informed that the failure to heat-treat products could result in contamination.

The judgement of the court was handed down on 23rd October 1992[77] Dr. Garretta was found guilty and was sentenced to four years in prison and a fine of FF 500,000 (US$ 100,00). Allain was sentenced to four years in prison, of which two years were

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[74] Laurent Greilsamer, *Le procès du sang contaminé*, (Paris: Editions Le Monde-Documents, 1992). This book published the main documents of the trial: the prosecutor's nearly 70-page charge, the judgement of nearly a hundred pages, and an account of the court hearings. Except where otherwise indicated the following citations are from these court documents

[75] Paugam, *op. cit.*, pp. 67-92.

[76] Greilsamer, *op. cit.*, pp. 159-172.

[77] *Ibid.*, pp. 215-305.

suspended. Director General Roux received a suspended sentence of four years' imprisonment. Dr. Netter was acquitted. The judgement also stipulated that the National Blood Transfusion Foundation, the parent organisation of the CNTS's, bore civil responsibility and was ordered to pay FF 9.2 million (US$ 1.8 million).

The spectacular criminal trial turned out to be a Pandora's box from which a seemingly never-ending legal dynamic emerged. The *délit d'épicier* was not enough to shake off death, so omnipresent in the affair[78]; hence the victims' disappointment and anger and the attraction of the indictment for poisoning. A public opinion poll found that 85% of those surveyed found the trial to be "unsatisfactory"; 75% demanded that the "politicians stand trial."[79].

The legal process was driven forward by the process of appeal. Convinced of his own innocence, Dr. Allain sought a rehearing and, as a consequence, compelled the appeals court to retry the cases of all four defendants. On 17th July 1993, the court of appeal confirmed the previous judgement, making only minor adjustments in the sentences. The court did, however, increase the plaintiffs' award from 9 to 15 million French francs.

Dr. Allain turned to the *Cour de Cassation*, the highest and last level of judicial appeal. But this appeal led to a remarkable turn of events. In June 1994 the reporting magistrate submitted a report to the criminal chamber of the court not only rejecting Dr. Allain's appeal but arguing that the facts of the case made clear that what was involved was not the offence of fraud but the crime of poisoning. Lawyers for Allain and Garretta declared that any move to retry their clients would produce an appeal to the European Court of Human Rights on the grounds that individuals may not be tried twice for the same offence, and an international group of scientific and medical notables, including several Nobel prize recipients, supported the embittered defendants. Nonetheless, the effort to press the president of the Republic to grant a pardon to the two blood officials was unsuccessful.

Nothing more tellingly underlines the continued search for the guilty parties deserving of punishment in the *scandale du sang* than the investigation opened by the Paris prosecutor's office in 1995, leading to the investigation of 13 people by early 1996 and 11 more by April 1997. This new criminal case caused much surprise when it was learned that even Jean-Baptiste Brunet, the AIDS epidemiologist who sounded the first and most persistent warnings concerning HIV contamination, was being investigated.

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[78] J.P. Delmas Saint-Hilaire, "La mort: la grande absente de la decision rendue dans l'affaire du sang contaminé par le tribunal correctionnel de Paris," *La Gazette du Palais* (9th March 1993).

[79] BVA Opinion Poll - Prévention Santé, *Revue Française des Sondages*, 82 (December 1992), pp. 3-8.

Unlike the earlier investigation, this effort was clearly aimed at extending the net of culpability.

The effort to bring to justice those responsible for the contamination of the blood supply is not restricted to civil servants but has reached the highest levels of the state. The first trial highlighted the role of the prime minister and the ministers of social affairs and health as well as the "pre-eminent role of their advisors"[80] But how was one to organise a trial of three high-ranking government officials ?[81] This question has engaged the parliament since mid-1992.

The blood victims, the press, and public opinion pressed for the trial of the "politicians," whereas the opposition parties saw an opportunity to discredit the Socialists. One of the accused, former prime minister Laurent Fabius, believed that a hearing of the charges would be desirable, although not before the *Haute Cour de Justice*, associated with trials for high treason. Believing he would be acquitted, he asked to be judged by a Court of Honour. Despite his effort to confront the issue directly, the political career of this top young socialist politician suffered.

Parliament encountered problems comparable to those of the courts but of even greater complexity in its attempt to institute legal proceedings. The process was characterised by missteps and was caught up in a more general constitutional reform, changes to the *Haute Cour de Justice* and the reform of the entire code of criminal law. Finally, four years after it first considered the matter, agreement was reached to commence an investigation under the charge of "complicity in poisoning." The entire process came to an unexpected conclusion when in March 1997 the public prosecutor, politically close to the conservative party in power (the RPR) since 1993 and Known for his opposition to the "criminalisation of public life"[82], declared that there were no grounds for prosecution. In his voluminous 400-page report, he argued that "complicity" implied the *active* participation in or intervention by the accused[83]. Although he held the prime minister ultimately responsible for his government and severely criticised the "apathetic" attitude of the health minister and the low level of involvement of the social affairs minister, he declared that such failings did not add up to complicity in poisoning. The ministers were *politically* responsible, and that was a matter to be dealt with by the electorate, not by the criminal courts. Although subject to extensive press commentary, the issue failed to provoke the passionate exchange that might well have occurred when the *scandale du sang* was still fresh.

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[80] "La mise examen des cabinets ministériels," *Pouvoir* [quarterly journal], 68 (Paris: Seuil, 1994).

[81] "Who is responsible? Who is guilty?" *Esprits* [monthly journal], 6 (1993).

[82] *Le Monde*, 13th March 1997.

[83] Jean-Françoiis Burgelin, Procureur général à la Cour de Justice de la Républque, *Réquisitoire* of 11th March 1997.

What seemed a final decision in March 1997 was soon revealed as yet another twist in a complex legal path. In June 1998, the public prosecutor formally requested that the *Cour de Justice de la République's* investigation commission drop the charges of complicity in poisoning (*complicité d'empoisonnement*) that were pending against former Prime Minister Laurent Fabius, former Minister of Social Affairs Georgina Dufoix, and former Minister of Health Edmond Hervé. In his request, the prosecutor stated that there was insufficient evidence that the decisions of those officials in the 1980s were motivated by industrial policy rather than public health, and reasonable grounds to believe that institutional pathologies of the French medical system caused the three individuals to be insufficiently informed about the danger of HIV-tainted blood.

The Prosecutor's request was reinforced by a July 1998 decision of the *Cour de Cassation*, France's highest court. According to the judgement, which came in a case involving HIV transmission through heterosexual contact, the crime of poisoning (*empoisonnement*) requires that those charged *intended* to kill. In raising the bar on poisoning charges by requiting the element of intent, the court settled a long-festering legal dispute over the definition of poisoning and struck a potentially fatal blow to the continuing investigation of physicians and other experts for their involvement in the blood scandal.

Advocates lost little time in responding to this legal setback. Within days of the decision, the association of transfusion recipients presented a new criminal complaint, arguing that health officials should be prosecuted on charges of "failure to assist people in danger" (*non-assistance à personne en danger*) "and failure to denounce a crime" (*non-dénonciation de crime*). On 17th July 1998, the investigation commission of the *Cour de Justice de la République* decided that it would, despite the request of the prosecutor, move ahead with the trial of the three former ministers. Rather than relying on the charge of complicity in poisoning, however, the commission will try them for involuntary manslaughter (*homicide involontaire*) and involuntary bodily injury (*atteintes involontaires à l'intégrité physique*), crimes with penalties of up to three years imprisonment and a $100,000 fine. It is possible that the former ministers will fight the court's decision, and the prosecutor may also appeal. Whatever their actions, it is clear that the conflict over HIV and blood continues to inspire legal innovation, and has been a vehicle for organised groups of patients to become a force in contemporary health politics.

Reforming the National System

The protracted legal struggles and the search for culprits overshadowed in some ways, the more mundane, but ultimately more significant, reform of the blood system designed to preclude future catastrophes. Reform had been on the agenda since the mid-1980s, given the need to make French policy compatible with that of the European Community. Finally, in the midst of the scandal, legislation reforming the blood system was passed on 4th January 1993. The previous institutions and decision-making structures - the National Blood Centre, National Health Laboratory, the Pharmaceutical Department of the Ministry of Health, and the national expert commissions -were all abolished. The supervisory authority of the DGS was reinforce and the functions of the former blood institutions redistributed to newly created bodies with independent expert authority.

Safety control procedures and market agreements for all pharmaceuticals, including blood and blood products, were placed under the responsibility of the new National Agency for Pharmaceuticals, a public body. The French Agency for Blood, a public administrative body, was given the responsibility of defining national blood policy and of monitoring its implementation. It was also given authority to grant official authorisation to the CTS's and to control their activities. An independent expert committee was established, the Committee for Blood Transfusion Security, to inform and advise the minister of health. A system of blood surveillance and monitoring with precise obligations regarding case traceability was also established. Blood centres were to be obliged by law to keep records enabling them to trace and identify each individual donation, donor, batch of blood and drug distributed, as well as each recipient. The law also required them to reinforce donor screening. Hospitals and clinics were obligated to inform every patient of a blood transfusion. Finally, efforts were made to contact all previous patients who had received transfusions during the period 1980-92 so that they might undergo HIV testing and receive compensation in the event of infection.

Autologous transfusion for non-urgent surgery was finally officially recognised and fully reimbursed by the national health insurance fund, overcoming the resistance to both autologous and directed donations, which had been viewed as violating the formerly sacrosanct principle of anonymous donation on a nation-wide basis. The catastrophe of AIDS had shaken the ideology that had placed at its centre the "good donor" as guarantor of national solidarity.

The new organisation of the blood sector was completed by a reform of university training. The Ruffie report of February 1993 provided new standards for the training of physicians who would serve as blood centre doctors[84]. The transfusion field, which was

[84] Jacques Ruffié,*Rapport sur l'enseignement, la formation et le recrutement et transfusion sanguine*, Report to the Minister of Health and Humanitarian Action, and to the Minister of National Education and Culture (Paris, 1993).

formerly attached to haematology, became an autonomous medical and scientific speciality within medical faculties. No longer was the management of blood to be seen as a sub-discipline of haemopathology. It was, rather, to be viewed as entailing the provision of healthy blood as part of public health. The training reform put an end to the "intellectual isolation"[85] of transfusion professionals.

Conclusions

The *scandale du sang contaminé* was unquestionably the most costly way, financially and politically, of reforming the blood transfusion system. The compensation law, the criminal case, and the personal intervention of President Mitterand were not enough to spare the Socialists from having to pay for the collapse of a national myth.

Many unsolved problems crystallised in the blood scandal. HIV arrived in a system with no helm, governed by a post-war ideology of national independence and solidarity. In the aftermath of the blood scandal, profound changes in the organisation of the blood system and in the politics of those dependent on that system occurred. The major shift in the policy network also amounts to a *redefinition of the symbolic value of blood*. The haemophiliac association now advocates a system of "selected, regular, HIV-negative plasma donors and, when possible, genetic production [of concentrates] without donation." (interview) Thus the blood sector is no longer viewed as the noble medical expression of social solidarity but rather as a technical, consumer-oriented domain. Blood products have lost their special status as a "part of the human body." They have descended into the category of normal drugs.

The consequences of the HIV/blood accident are numerous and far reaching. The criminal case as well as the fall of the war-born celebration of blood donors has marked the end of the position that French physicians have held in society since the Third Republic. The entire transfusion sector has been modernised by profound reform, as has the organ transplantation system and the entire replanning of surveillance for pharmaceutical products. Public health structures and institutions have been reinforced. A Higher Committee for Public Health has been created and entrusted with regular reporting to the government on public health issues.

The significant mobilisation of the legal system also had far-reaching consequences. The relationship between medicine, science, and law has been adjusted. The ensemble of legal proceedings condemned an obsolete conception of science that demands irrefutable evidence before action can br taken by officials responsible for public

[85] Hermitte, *op. cit.*, p. 18.

health[86]. Out of the blood controversy emerged a new notion of the place of risk in administrative law. The need to act in the face of *potential* risk was established (*principe de précaution*).

The changes and reforms were not, of course, solely the result of the HIV/blood catastrophe; the need for change existed long before. The blood scandal, with its important media mobilisation helped to remove the obstacles to reform at many levels, most notably within the political system. Precisely because the tragedy of blood in France could not be traced to international factors, precisely because it was "home-grown," did the *scandale du sang* have such profound ramifications.

[86] *Ibid.*, pp. 286-350.