

RESPONDING TO THE HIV-TAINTED BLOOD CONTAMINATION IN ITALY (1996)

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This working paper was presented by the author – then a fresh Ph D Student in Comparative Law – during a seminar held at the Castello di Santa Maria della Novella (Florence) on July 18, 1996. The seminar was part of an International Research Project entitled “Blood Transfusions and AIDS: Common Threat, National Responses”, led by prof. Ronald Bayer (Columbia University – New York) and prof. Eric Feldman (then New York University – New York). Funding for the project was provided by the Toyota Foundation and the Japan Foundation, Center for Global Partnership. Among the participants to that “castle” seminar I like to remember, with gratitude for the challenging atmosphere that they contributed to create, David Kirp, Dorothy Nelkin, Theodore Marmor, John Ballard, Erik Albaek, Margaret Sommerville, Norbert Gilmore, Monika Steffan, and many others from a host of different countries. I drew heavily on this paper when I published a substantially shorter version of it as a chapter entitled *Blood, Bureaucracy, and Law: Responding to the HIV-tainted Blood Contamination in Italy* in E.A. FELDMAN, R. BAYER (eds.), *Blood Feuds: The Politics of Medical Disasters*, Oxford, New York, Oxford University Press, 1999. The text of this paper has been stored in my hard disk for more than 11 years. I believe that some of the data that I presented more than 10 years ago to an international audience of scholars may still be of some interest today, especially because in Italy the legal struggle behind the facts explored in this paper is not over yet (as of September 2007). This paper is published as it was drafted in 1996 without additional (substantial & formal) review, so please forgive the many mistakes that it may contain.

“The proposition that the existence and nature of a tragic choice depends on which society confronts the tragic choice is a truism -- after all, whether a value is regarded as fundamental, to say nothing of the facts of scarcity, will vary from society to society -- and one may justifiably balk at an extended discussion that professes to support that proposition. What may prove more interesting, however, are examples of societies which present rough concurrences with regard to the status given to the value of life and equal treatment, and approximate equivalences of economic conditions, but which seem to display quite different approaches to a problem all regard as tragic. Such an exercise should act to show the incandescent role of a society’s own conception of the values at stake and of the legal tradition which must cope with the conflict“¹.

Introduction

July 16, 1982 is a date which will never be forgotten by the world’s bleeding disorder community. The Center for Diseases Control of Atlanta (CDC) alerted that three hemophiliacs, factor VIII massive recipients, had died as a result of the typical pathology which at that time was known as a sign of a new, deadly disease².

The day before, coincidentally, the most prominent experts and authorities of the Italian blood system were reunited in Rome at the “First focus panel on the national blood plan”. The Director of the Italian Superior Health Institute (ISS) officially presented his proposal to solve the endemic shortage that ever since had affected the Italian blood system. Incidentally, he made mention of the controls over blood products and stated:

“...without doubt, since blood products require high technological standards for their manufacture, they are industrial pharmaceutical specialties. They are subject to authorization and therefore subordinated to controls by the Health Authority... [These controls are] to be performed on the productive plants previously authorized, on raw plasma and on each batch of final product. Today, however, controls on the original raw plasma by the [Italian] health authority is practically impossible, either for lack of regulations such as those enacted by the American Food and Drug Administration for the collection of “original plasma for further fractionation”, or because Italian industries, given the absence of such regulations, often prefer to import half-purified plasmatic fractions from abroad”³.

¹ G.CALABRESI, P.BOBBIT, *Tragic choices*, 1978, New York, at 177.

² CDC, *Pneumocystis carinii pneumonis among persons with hemophilia A*, in *Morbidity and Mortality Weekly Report*, 1982; 31:365-7; CDC, *Possible transfusion associated acquired immune deficiency syndrome (AIDS)*, *Ibid.*, 1982; 31:652; J.F. DESFORGES, *AIDS and preventive treatment in hemophilia*, in *N.Eng.J. of Med.*, 1983, 308:94; *Preventing AIDS transmission: should blood donors be screened?*, in *Medical News*, February 4, 1983.

³ F.POCCHIARI, *Il problema sangue: proposta di soluzione*, paper delivered at the “Giornata di studio sul piano nazionale sangue, Rome”, July 15, 1982, in *La trasfusione di sangue (hereinafter: TS)*, 1983, 4:274, 283.

These admissions sound today as a lost warning. But at that time, adequacy was still the "magic word" in the Italian blood system. The issue was to improve the availability of whole blood and, above all, of plasma.

At the beginning of the '80s, the Italian supply of whole blood could meet only about 2/3 of what was estimated to be the optimal quantity for the national needs. The shortage of plasma was much more striking. 95% of the vital liquid from which the hemophilic factors could be obtained had to be imported⁴. This dependency on imported plasma was a source of concern for the Italian blood policy-makers. Further to the financial burden, there was the fear that the national inability to supply plasma for industrial production of coagulation factors might have exposed Italy to unexpected shortages.

Nobody could then foretell that import-dependency in plasma could also be an extremely dangerous pattern in the event that a new viral threat should appear in the bloodstream. Aware of the inability to perform adequate controls on each batch of imported blood products, experts at that time blindly relied on the "prestigious" severity of the American regulations.

Not even Pier Mannuccio Mannucci, the Italian internationally renowned expert on clotting disorder pathologies, could imagine that this importation was already slowly carrying a lethal virus in the immune systems of many Italian hemophiliacs. His speech, as Scientific Secretary of the Italian Hemophilia Foundation (IHF), at the International Conference on Plasmapheresis held in Milan two months before the CDC warning, reveals unconditional trust in the American blood and plasma regulations:

"(I)n Italy and in other countries plasmapheresis is seen by the medical world, and particularly by the blood bankers, as a sort of devil. Its image is associated with crowds of undernourished people from developing countries, queuing up in front of dirty blood banks to donate their blood only to be deprived of their scanty plasma proteins for a few dollars. The medical profession must be aware that such 'wild' plasmapheresis has now been abandoned practically everywhere, and that plasma made available to commercial manufacturers comes from plasmapheresis stations, fully controlled and approved by national regulatory agencies, such as the Food and Drug Administration in the USA (...) On the other hand, even those not giving credit to these imaginative stories and dreadful pictures are nevertheless deeply concerned with the fear that intensive plasmapheresis might be dangerous for the health of the donor (...). These preoccupations must be dealt with and dissipated because there must be a strong guarantee that the health of those who give their plasma for humanitarian purposes is not endangered by plasmapheresis"⁵.

In that crucial summer of 1982, therefore, Italy was still facing the structural inadequacy of its blood system to overcome the shortage of blood and plasma supply. The

⁴ POCCHIARI, *ibid.*, 275.

⁵ P.M.MANNUCCI, Availability of plasma fractions for therapeutic use in Italy - Proceedings of the International Conference on Plasmapheresis 82, Milan, 27-28 May 1982, in *La ricerca in clinica e laboratorio*, 1983, 13:1. See also, in the same occasion, the reassuring picture depicted by J.L.TULLIS, Current plasmapheresis practice in the United States, *Ibid.*, 11; and L.M.ALEDORT ET AL, Impact of factor VIII deficiency on clotting factor utilization in the United States, *ibid.*, 33.

regulations that shaped the system had been codified 15 years before, and the debate over the need for a radical reform had been going for years.

Meanwhile, the Italian blood system, like all others systems of the industrialized nations, had had to confront a spanking new technological challenge. The advent of industrial AFC (Antihemophilic Factors Concentrates) in the '70s revolutionized the relationship between a class of chronic patients and their disease for the first time in the history of medicine. Updating the blood system in order to enable it to handle the increasing demand for this new therapeutic reality was the challenge.

Structurally bound to a web of detailed technical regulations, which had been conceived according to the scientific knowledge of the second half of the '60s, the Italian blood system was caught completely unprepared to accept this technological and organizational challenge. Its guidelines were inspired by a rigid paradigm of bureaucratic centralism. These not only ignored the peculiar socio-anthropological features emerged during the early history of the Italian blood system, but proved to be refractory to technological development.

The Italian Blood System in Historical Retrospective

The development of the Italian blood system was originally spontaneous and entirely based upon a free associative tendency. After Landsteiner's crucial discovery of the Ab0 system at the beginning of the century, and the impetus given to the therapeutic use of blood by the First World War, the few Italian hospitals that could provide blood transfusions had lists of paid suppliers. The mercenary practice fixed the prices and a single transfusion could cost the equivalent of several months' of an average wage.

The first initiative to promote the culture of voluntary blood donation was prompted by the enthusiasm of a Milanese physician, Davide Formentano, who in 1927 organized the first group of unpaid donors around his hematological practice. This pioneer associative undertaking led, two years later, to the official foundation of AVIS (Italian Voluntary Blood Association), the first association of its kind in Italy. AVIS's original goals were to satisfy the growing need for blood by organizing a network of regular donors under constant medical control, to fight the blood trade, to spread the idea that blood is a natural and anonymous gift and to enhance scientific knowledge of transfusion practice. These principles have, since then, shaped the development of the Italian voluntary blood donor organizations.

Closely supported by the pioneers of the Italian transfusion medicine, AVIS quickly developed in the Northern regions as a unique example of a civic and laical associative endeavor in a society still deeply imbued by Catholic clericalism. Soon this spontaneous growth of the culture of voluntary blood donation was endangered by the general regulatory plan with which the fascist regime sought to structure the public health administration according to its own ideology. Mussolini himself requested Formentano to add the letter F (for fascist) to the acronym of the new-born association.

The Duce's desire was left unfulfilled. Nevertheless, after the *Regio Decreto* (King's Decree) issued in 1934, not only was the collection of blood and the transfusion practice embedded into a pyramidal system of authorizations and administrative bodies (ranging from municipalities to the ministerial buildings that had been just erected by the regime in Rome), but also the role of professional donors, who supposedly earned their livelihoods by selling blood, was legally acknowledged.

Apart from the fascist policy of admitting the pricing of blood, the increasing therapeutic use of the vital liquid pushed legal scholars of the time to speculate on its juridical nature. The scant availability of blood supply brought Francesco Carnelutti, one of the most prominent legal scholars of the time, to argue in favor of legalizing the taking of blood against the donor's consent, if this was necessary to save the recipient's life⁶.

According to the absolute concept of ownership inherited from Roman law, blood was legally considered to be the property of the donor also when parted from the donor's body, although the Civil Code then in force did not explicitly regulate the use of the human body or parts of it. The issue caused a lively debate before the enactment of the new codification in 1942.

A draft proposal generally stated that an act of self-deprivation, implying a prejudice to the human body, was permitted if not contrary to the law and morality. But, once enacted, this text was amended solely to take into account the human body's ability to regenerate blood. By endorsing the idea that only "an act of disposition implying *permanent* prejudice to the human body" was against the law⁷, the newly enacted Civil Code (which today is still in force) clearly stated that the legislators wanted to encourage the transferability of blood. But the general rule did not bind policy-makers to a given stance toward the philosophy of the blood collection system: either a market approach or a generosity-based system could be conceived for the future⁸.

The drama of the war heightened the altruistic spirit of blood donation. After the collapse of the fascist public health structure, the new-born Italian Government attempted to restructure the blood system. A monopoly over blood collection was granted to the Italian Red Cross, which was then the only non-profit health organization officially recognized by the government. This attempt represented a threat for the spontaneous and voluntary-based commitment of AVIS. After a few years of political pressure, the Red Cross' legal monopoly over the sector was abrogated and AVIS was recognized by the Government as a non-profit public institution devoted to the spread of the culture of voluntary blood donation.

Thereafter, and for almost twenty years, a long regulatory silence fell on any blood-related matter. Paradoxically, this was a time of profitable cooperation between donor associations and the first transfusion centers, which, by the end of the '40s, were being autonomously organized by the major hospitals of the country. AVIS, which today is still by far the leading Italian non-profit organization in the voluntary collection of blood, structured itself on a territorial basis.

A strong presence in the local community became thereafter the pattern that permitted a slow but steady diffusion of the culture of voluntary blood donation in the country. On the AVIS example, smaller organizations of blood donors started to operate, some with religious inspiration like the FRATRES, others with the aim of serving the needs of big hospitals.

The Italian Immuno-hematology and Blood Transfusion Society (SIITS-AICT, today SIMTI) was founded in 1954⁹, when a group of physicians, who managed the few

⁶ F.CARNELUTTI, Problema giuridico della trasfusione di sangue, in *Il Foro italiano* (hereinafter: *Foro It.*), 1938, IV, 89.

⁷ Art. 5 of the Italian civil code.

⁸ F.DEGNI, Sulla trasfusione obbligatoria del sangue (a rejoinder to prof. Carnelutti), in *Foro.it*, 1938, IV, 130.

⁹ G.REALI, *La storia della medicina trasfusionale*, in *TS*, 1995, 2:72.

transfusion centers which then existed in Italy, decided to create a body similar to the American blood banks association. Their endeavor was to draw up uniform guidelines and to set up operational standards for the transfusion practice.

In those years the complexity of blood transfusion grew proportionally with scientific and technical advancements. New knowledge in immunology solved many of the problems of blood incompatibility, while the introduction of new instruments revolutionized techniques. Direct transfusion was abandoned in the '50s in favor of special vacuum-prepared glass flacons with preservative solutions, which permitted a longer storage of blood in refrigerators¹⁰. The introduction of these technological improvements was left to the discretion of each head of local transfusion centers. Yet in 1959, only three transfusion centers in the North could provide lyophilic plasma.

The lack of a national policy explains the uneven development of the blood system across the country. The entire health care system was then lacking central coordination and even the establishment of the Health Ministry in 1958 left the blood sector substantially unregulated¹¹. In the North, towns like Turin could already boast a blood collection center organized as a replica of an American blood bank, working in close cooperation with the local blood donor association. By contrast, in the South the situation was far from satisfactory.

Indeed, the “gift philosophy” toward blood has always been much more culturally accepted in Northern Italy than in the South. This differing attitude between the North and South is even to this day a major problem for the Italian blood collecting policy. It reflects a deeply rooted difference in the social dynamics which exists between the individuals and their local community.

It is, in fact, widely assumed that group loyalty encourages voluntary blood donation. The members of the group are willing to perform the altruistic act of donating blood for free, if they believe that some day this generosity will be returned by the group¹². In the North this social pattern has traditionally proven to work within the local community, because of the strong sense of membership that links individuals to their community. But this has never been the case in Southern Italy, where group loyalty is shifted to the family and its entourage. Therefore, blood donation was likely to be performed in the South only when a member of this close-knit parental community was in danger of life and was the direct beneficiary of the gift¹³.

Many of the difficulties encountered by the North-based AVIS in establishing roots within the social tissue of the Southern regions was explained by this unwillingness of considering blood donation as an “anonymous gift”.

The “group loyalty” argument, then, would also explain why in those years (again, particularly in the South) the work-place was a favorite environment for blood collection. Within large firms, self-organized groups of workers promoted blood donation days to cover the occasional need for blood by fellow-workers or a member of their family.

¹⁰ W.MOLLA, Organizzazione e funzionamento di un centro trasfusionale, in V° corso di aggiornamento per medici sulla trasfusione di sangue, 1959, AVIS Milan, 125.

¹¹ Law 13 March 1958, n. 296. As its institutional role, the ministerial body also supervised the Istituto Superiore della Sanità (ISS), established as national medical research institution in 1952.

¹² M.DOUGLAS, No free gifts. Introduction to Mauss's essay on The gift, in Risk and Blame: Essays in cultural theory, 1992, London - New York, 155.

¹³ G.CLERICO, Raccolta e allocazione di sangue: donazione, mercato ed intervento pubblico, in Rassegna giuridica della sanità, 1994, IV, 140.

The other side of the coin was the sale of blood. The mercenary practice was not yet legally prohibited and was still far from being eradicated. In emergencies, the beneficiary of a blood donation would have felt the moral obligation of providing a reward. The lack of educational efforts to increase the individual's "docility" toward blood giving¹⁴, combined with the chronic shortage of blood, explained the flourishing of a vicious black market. The precious *oro rosso* (red gold) could give rise to extortion, when unscrupulous blood merchants would take advantage of the vital need for the donation of a particularly rare type of blood. The image offered by the director of a Southern blood bank is impressive:

“(S)ometimes blood blackmarketeers loiter at the entrance to the transfusion center, waiting to contact the patient’s relatives. After negotiating a price they present themselves as friends of the patient. For us it is not easy to determine whether they are engaged in illegal transactions ...”¹⁵.

In short, in the post-war period, during the ‘50s and the early ‘60s, the Italian blood system remained unregulated. Its development depended solely on the cooperative efforts of non-profit blood donor organizations and Italian transfusion doctors. Nevertheless, although contending with burgeoning differences among different parts of the country, the blood system evolved by benefiting from international scientific and technical exchanges (the congress of the International Society of Blood Transfusion was held in Rome in 1958, while Germany, England and the USA were the favorite destinations for young physicians who wanted to improve their skills).

By the mid ‘60s, the Italian Government had increased its institutional control over the National Health Service, by strengthening the bureaucratic structure of the Health Ministry. A strong call for the introduction of uniform standards and regulations was made by both the medical class and representatives of the voluntary blood donors associations.

Blood and Bureaucracy: The 1967 Act

Following an intense and lengthy debate in the legislative arena, the “Collection, preservation and distribution of human blood” Act came into force in 1967¹⁶. This law, and the set of ministerial decrees which completed its general provisions, henceforth regulated virtually every aspect of the Italian blood system for twenty-three years. As of that time, the “juice of life”¹⁷ became a matter of State, justifying the Health Ministry’s supervision of its collection, processing and distribution. But, above all, this long-awaited State intervention marked the start-up of a stream of complex regulations. From then onwards, this stream will never dry up.

According to the tradition of the Italian structure of the public administration (which historically date back to the fascist era) the blood system was once again

¹⁴ The first government-financed TV commercials on blood donation appeared on Italian television as late as 1971.

¹⁵ N.SCARANO, Il dramma della raccolta di sangue [The blood collection drama], in *Nel mese*, 2, 1976, 11.

¹⁶ Law 14 July 1967, n.592.

¹⁷ P.CAMPONESI, *Il sugo della vita: simbolismo e magia del sangue*, Milan, 1984 (now: id., *The Juice of Life*, New York, 1995).

hierarchically organized. Provincial blood boards were to be appointed by the Health Ministry as local agencies with the task of administering blood collection and distribution on a local basis. The broad composition of these boards reflected the view that blood administration was a matter of public interest, and therefore had to be democratically supervised by a wide range of representatives of the so-called “civic society”.

No wonder, then, that these provincial bodies were conceived as small parliaments, where, besides blood experts and delegates from the blood donor associations, sat representatives of the army and even of the local health workers’ labor unions. The obvious result was an administrative elephantiasis which greatly impaired the efficiency and decision-making of these bodies.

Conceived according to the “rule of legal bureaucracy”¹⁸, the system depicted by the Act could not take into account the local differences that could be discerned in the Italian attitude toward blood donation. Therefore, although formally establishing the same kind of local structures throughout the country, the law failed to envisage a system of coordination capable of balancing inter-regional differences in blood collection.

The provisions addressed to regulate the manufacture and distribution of blood products, together with those describing the relative administrative controls, aptly expressed the bureaucratic nature of the system. According to each field of competence, provincial doctors, provincial blood boards, the Superior Institute of Health, up to the person of the Health Minister, were called upon to express advice or to release formal authorizations. From then on, every new blood or serum product was to be subjected to ministerial authority.

The “Kafkaesquian bureaucracy” of the newly established system was characterized by a detailed set of second-level regulations. For example, legal provisions itemized the standard pieces of furniture that had to equip transfusion centers, whereas other provisions prescribed that to obtain plasma for further fractionation no more than twelve flacons of blood could be pooled. These technical regulations were condemned to quickly become obsolete and hamper the acquisition of new techniques. For instance, determining mandatory procedures for the production of antihemophilic cryoprecipitates, limiting to codified standards the exploitability of plasmapheresis, or prohibiting the storage of blood in plastic sacs became within a few years a legal non-sense.

With respect to the selection of the blood donors, the law depicted the safety measures of the time. A major role was assigned to the general examination of the donor by the transfusion expert physician. Prevention of possible viral contamination relied on medical interviews, in order to bring to light previous pathologies in the donor’s medical history.

The venereal disease reaction was the only test legally prescribed, but the Act failed to assign an autonomous power of rule-making to the Health Ministry, in order to render the future introduction of compulsory tests simple and timely¹⁹.

¹⁸ I use this definition to summarize what Joseph LaPalombara has perfectly explained to non-Italians: “...Italy is a lawyer’s paradise, and not just because Italians admire forensic skills. A prevailing lawyer’s mentality dictates that all possible contingencies regarding public policies must be anticipated and codified. This means that people are forever in search of what nuance “The Law” will or will not permit (...) one has the impression that without the *Gazzetta Ufficiale*, which publishes weekly updates of the country’s many legal codes, the country, or at least most of its institutions and transactions, would simply fall apart” (emphasis added), id., *Democracy Italian Style*, 1987, New Haven-London, 209.

¹⁹ According to the Italian constitution, a parliamentary law is required to enable the executive power to regulate a given matter by means of ministerial decrees.

Import of blood and serum products was subjected to a complex procedure. Foreign products had to be tested by an Italian pharmaceutical company or health facility previously deemed qualified by the ISS to perform such tests properly. Once authorized, the importer was assumed legally responsible for the foreign product's compliance with the quality standards set out by the Italian law for that given product²⁰.

Concerning the gratuitous nature of blood, the law did not take a clear stance. Although endorsing the principle that "blood can not be considered source of profit", the law ambiguously envisaged the role of the "professional donor", who was defined as someone remunerated for supplying blood. A standard price per donation was supposed to be quantified by a future ministerial provision, which never followed. Consequently, the pricing was left to the Provincial Boards.

But what really betrayed the expectations of volunteer donors was that the 1967 Act did not set forth a criminal provision to punish the mercenary practice. As a result, the only crime that could have deterred the activity of a blood merchant was the crime of usury, set out in the penal code. But sentencing for such a crime in the case of blood trade required evidence that the price asked for blood was "manifestly exorbitant", according to the jurisprudence. Such a proof resulted very difficult to provide once in criminal court.

A separate statute²¹, instead, granted what the AVIS' representatives had been lobbying for. In order to encourage blood donation the worker's right to a day of rest when giving blood was legally acknowledged. Employees giving their blood for free could receive their daily wages from the employer, who was then reimbursed by the State.

In the space of a few years, every blood-related matter in Italy had received its rule.

However, an important institutional factor very soon further complicated the administration of the blood system. In 1972 the State transferred a significant portion of its legislative and administrative functions to the Regions, thereby finally applying a constitutional provision that had remained inoperative since the adoption of the Constitution in 1948. As a consequence, the health sector was gradually decentralized and the newly-established regional councils acquired an important role in the administration of the health care system.

This transfer entailed a delicate period of transition during which the complex system of checks and counter-checks typical of the Italian centralized ministerial bureaucracy had to be coordinated with the new regional order²².

As early as 1975, when it was still unclear whether the new regional legislative councils had the power to regulate matters concerning blood, some regions started to promulgate acts which promoted the local activities of the blood donors associations. Each local association was to receive financial aid (covering the collection-related costs) proportional to the quantity of blood supplied to the regional health facilities²³.

Following the administrative decentralization of the '70s, the regionalization of the health system exerted a strong deal of influence on the blood sector, enabling each region

²⁰ Ministerial Decree (hereinafter: DM) 15 September 1972.

²¹ Law 13 July 1967, n.584.

²² S.CASSESE, The higher civil service in Italy, in E.N.SULEIMAN, *Bureaucrats & policy making. A comparative overview*, 1984, New York-London, 66.

²³ S.SECHI, *Iniziativa legislative regionali in materia trasfusionale*, in *Atti del convegno "Giornate di studio sui problemi della trasfusione e della donazione di sangue*, 1978, Bari, 67.

to develop its own system in accordance with local needs and, especially, with its own tradition toward free blood giving.

In 1978 the Health System Reform Act stated that the guidelines regulating transfusion, blood collection and blood derivatives production had to remain nationally standardized, owing to their importance in order to ensure uniform health conditions throughout the country²⁴. State authorities therefore retained their legislative prerogative over the blood sector. Yet, despite this general principle, it became obvious after the 1978 Reform that the regulation of the blood collection system urged coordination with the new regional order²⁵.

The reform itself made reference to a *Piano Nazionale Sangue* (National Blood Plan), which would have made this coordination possible. But for the Italian Parliament this provision remained only a good intention: the plan was never realized and not until the 1990 reform did the Italian blood system become legally structured, according to the administrative autonomy of the regions.

The advent of administrative regionalization, therefore, did not affect the history of cultural misgiving toward blood donation of the Southern regions²⁶. Rather, it widened the geographical heterogeneity of the Italian blood system. Taking advantage of the new autonomy, some Northern regional administrations, like those of Tuscany and Lombardy, promptly conceived a system of regional coordination based on a network of agreements between transfusion centers and donors associations. This permitted to increase efficiency in blood collection by forestalling local blood surpluses and deficits²⁷. Lombardy also established a regional center for the production of blood derivatives²⁸.

But the same prompt intervention of regional administrations could not be observed in the South²⁹. In 1983, Southern regions were still a long way from achieving local adequacy in whole blood supply, whereas plasma was supplied in negligible quantities³⁰.

The Italian Bleeding Disorder Community in “the Age of Trust”.

Until the '50s, hemophilia had been treated with transfusions of large quantities of plasma. Hemophiliacs were condemned to long periods of hospitalization and their life expectancy was extremely low³¹. In Italy, cryoprecipitates therapy became available in

²⁴ Law 23 December 1978, n.833.

²⁵ M.ZANA, Il servizio trasfusionale tra tecnica e normativa: il parere del giurista, in *Rivista italiana di medicina legale* (hereinafter: RIML), 1985, 834.

²⁶ On the uneven capacities of administration displayed by regions when regionalism was implemented in Italy in the early '70s, see F.SPOTTS, T.WIESER, *Italy. A difficult democracy*, Cambridge, 1986, 226 and the analytical study of R.D.PUTNAM, R.LEONARDI, R.Y.NANETTI, *La pianta e le radici*, Bologna, 1985.

²⁷ In 1978 the Italian transfusion centers provided only 2,500,000 of the 26,000,000 AFC consumed by Italian hemophiliacs. 80% of this scarce contribution to the national needs was made by only four Northern regions. See A.GHESSI, R.DE BIASI, *Disponibilità e utilizzazione dei concentrati emofilici in Italia*, 1978, Milan (source: IHF).

²⁸ Regional Law 7 June 1980, n.80.

²⁹ Compare the gloomy picture of the Apulia situation depicted in 1978 by the director of the local hemophiliac center: N.CIAVARELLA, *Atti convegno “Giornate di studio sui problemi della trasfusione e della donazione di sangue*, 1978, Bari, 61.

³⁰ See DE BIASI ET AL., *La carenza di sangue nelle regioni meridionali [The shortage of blood in the Southern regions]*, in TS, 1983, 1.

³¹ In the '50s, 90% of the Italian hemophiliac population died before entering their twenties, C.RIZZO ET AL., *Emofilia e lavoro: contributo statistico e considerazioni medico legali*, in *Difesa sociale*, 1992, 6:51.

the latter half of the '60s. A dose of factor VIII or IX could be obtained by pooling plasma from small groups of donors. In those years, the relatively simple technology used in this "artisan" manufacture of clotting factor concentrates became available at several transfusion centers. But the problem was the extreme paucity of fresh plasma. And the restrictive technical standards imposed on the exploitation of plasmapheresis on donors, which were issued at the beginning of the '70s, did not seem designed to address the issue.

Besides, at that time, from a medical point of view it was unclear who had professional competence in treating the hemophiliac patient. Orthopedists treated arthropathies, which affected hemophiliacs as consequence of internal hemorrhages. Transfusion expert physicians produced and administered cryoprecipitates. Hematologists, of course, were competent *ratione materiae*.

But the lack of coordination among these three categories of physicians reflected on the patients. Consequently, hemophiliacs had a compelling need for the establishment of *ad hoc* facilities for the treatment of their disease. When, on the eve of the '70s, the echo of the new "American treatment" (the industrial Anti Hemophilia Factors) spread among Italian hemophiliacs, this lack of landmarks resulted in a dilemma for many of them. To trust the physician who had them in charge and was still administering the "old" cryoprecipitates? Or, rather, to try to get these new concentrate factors by traveling to a (sometimes very distant) health facility, where, it was said, this new therapy could be obtained?

It was in answer to these problems that in December 1969 a heterogeneous founding group, composed of parents of hemophiliac children, benevolent rich ladies from the Milan high society and some hematologists and transfusion expert physicians, established the *Fondazione Italiana dell'Emofilia* (Italian Hemophilia Foundation, hereinafter: IHF) in Milan.

Following the example of other national hemophiliac organizations, which had established the World Federation of Hemophilia in 1963³², the goals of IHF were to support and to raise funds for scientific research on the disease, to inform and educate hemophiliacs and their families, as well as to campaign for improved clinical and social assistance for the class. The new-born organization did not adopt the legal rules of a democratic association among hemophiliacs³³. The choice of adopting the legal status of a *Fondazione*, illustrates how important it was for the founding members to obtain formal acknowledgment from the Italian State³⁴. This would have permitted the IHF to assume

³² Current Studies in Hemophilia, Proceedings of the 3rd Congress of the W.H.F., in Bib. Haemat., 1966, 26.

³³ In the Italian legal system a *Fondazione* is a non-profit organization characterized by the settlement of a fund legally bound to the pursuit of a given beneficial purpose. Conceptually, it is far more similar to a trust than to an association. In a *Fondazione* the new members may support its beneficial goals, but are not entitled to vote (or to be appointed as) the executive administrators of the organization. This inhibits the free associative dynamics, which instead may take place within the legal framework of an association. Asked to explain why a non democratic institution was chosen to represent the hemophiliacs' action, the current President of IHF (who has held the office since 1969) answered that the choice was due to the fear that, once organized in an association, external forces could gain control of the hemophiliac organization, by manipulating the majority of the votes. This choice, he revealed, proved farsighted because pharmaceutical companies in several occasions had tried to gain such control.

³⁴ To begin to operate, a *Fondazione* must be recognized by a ministerial decree. Although this implies that the government has the power to supervise the activity of the organization, by future verification that the fund is administered according to the goals established in the act of settlement, this

an institutional vest with which to press the Government for an improved national health policy toward hemophilia. From the very beginning, the IHF's action would be constantly characterized by the search of institutional visibility, to be pursued adopting a strategy of collaboration with institutional authority.

The first IHF national congress was held in Milan in 1970. The Italian Government was openly requested not to further delay the implementation of a special policy for hemophiliacs, pointing out the example of France. Beyond the Alps, it was pointed out, the *Association Française des Hémophiles* had succeeded in obtaining from the Government the creation of a national network of specialized centers for the bleeding disorder community, as well as special forms of support for the hemophiliacs' families³⁵.

The need for vesting the IHF's claims with legal arguments was fulfilled by resorting to a law enacted in 1961³⁶. This law set out the tasks of special health care facilities which were to be established for the care and treatment of diseases considered of social relevance. The task of determining which disease could comply with the special provisions set forth in this existing statute was delegated to the Health Ministry.

Therefore, the first political goal of the IHF became to have hemophilia legally declared a *malattia sociale* [disease of social relevance]. Taking advantage of this preexisting legal framework, it proved relatively easy for the IHF to obtain political attention for its claim. In 1972 a Health Ministry decree released the financial support for the establishment of a regional-based network of specialized medical centers for the study and treatment of hemophilia³⁷.

The final choice for a decentralized structure came at the end of a strategic dispute between the two classes of specialized professionals who participated in the scientific committee of the IHF. Transfusion expert physicians were in favor of the establishment of a national center specialized in the treatment of hemophilia in Rome, in order to concentrate research activity and AFC production in one place on a national level.

By contrast, hematologists were convinced that only the most effective diffusion of special centers throughout the country could reduce, if not eliminate, the phenomenon of commuting that had, until then, characterized the hemophiliac's need for constant medical assistance. By prevailing in this dispute, hematologists gained a definitive professional and institutional leadership in the treatment of hemophilia. The key positions as heads of the newly established centers were to come from their ranks.

These centers became landmarks for the hemophiliac population: it was at these facilities that patients could receive the AFC which in the first half of the '70s were starting to be imported. Since supplementary regional regulations were necessary for the establishment of these centers, their implementation was uneven throughout the country. Nevertheless, by the year 1984, 31 centers had been established in Italy.

Moreover, again at a regional level, hemophilia self-treatment became possible, enabling patients (or an assisting person) to intravenously administer blood products. Industrial AFC could be stored in ordinary refrigerators, and allowed hemophiliacs to maintain personal stocks of concentrates at home. The hospital-based therapy with

formal act of recognition also has an important side effect. The organization, in fact, appears vested of institutional authority. And this was the first goal of the IHF founders.

³⁵ The final resolution of the congress became an open letter addressed to the Health Minister on May 18, 1970.

³⁶ President of the Republic Decree (hereinafter: DPR), 11 February 1961, n.249.

³⁷ DM 12 June 1972.

cryoprecipitates could be replaced by prophylactic treatment. The dream of preventing the occurrence of hemorrhages through periodical inoculation of AFC had become finally possible. Regional Acts provided for courses to be held in authorized hospitals, where hemophiliacs patients or their relatives could learn how to administer AFC³⁸. Only on successful completion of such training programs could patients obtain the medical prescriptions required to obtain AFC in pharmacies.

In the second half of the '70s the "miracle" of the new concentrate factors was bringing about a radical change in the life-style of the Italian hemophiliac³⁹. It may appear secondary, but for the first time children, who until then had been compelled to live in a glass bowl, could start practicing sports⁴⁰. Under the auspices of the IHF, local hemophiliac committees and associations were created at every regional center for the treatment of hemophilia.

The information and advice on the disease that IHF members could receive at home via the national newsletter of the organization⁴¹, but also the mere fact of having the opportunity to meet at the centers other people in the same condition, gave hemophiliacs (and their families) a sense of being part of a community that never existed before.

A quick process of group identification took place among individuals who were discovering that to be hemophiliac did not mean solely being a patient. The extraordinary reduction of the impairment effects of arthropaties, the newly acquired freedom from the dependence on constant assistance, offered to the hemophiliac the perspective of mingling with others and the possibility of attending social activities. The physical impairment, the external status associated with the disease, could no longer be detected⁴².

The new social dimension of hemophiliacs also had other positive effects, perhaps less visible to the external world, but extremely important for their private life. It wasn't rare, until the '70s, that the unexpected birth of a hemophiliac child was viewed, especially by the father, as a sort of "blood betrayal". In such cases the education and care of the children were likely to be left to uncles or grandfathers. The lack of parental acceptance persisted even during adolescence, resulting in an additional psychological burden for the adult hemophiliac. Meeting other hemophiliacs' parents, learning from their experiences, acted as a natural therapy for these phenomenons of psychological refusal⁴³.

In 1975, the then existing public health insurance funds (which in 1978 were amalgamated into the National Health Service) included AFC in their drug lists, qualifying these pharmaceutical products as "life-saving medicines" to be provided free of

³⁸ Lombardy was the first region in Italy to enact this kind of regulation, see Regional Law 12 June 1975, n.89.

³⁹ P.M.MANNUCCI, Z.M.RUGGERI, Hemophilia care in Italy, in *Thrombos.Haemostas.*, 35:531-536, 1976.

⁴⁰ Gli emofilici possono svolgere attività sportiva [Hemophiliacs can perform sport activity], in *Il Corriere della Sera* (hereinafter: CDS), 24 June 1975.

⁴¹ The first *Manualetto* [handbook] containing a detailed set of therapeutic information for the hemophiliac was published by IHF in 1972. From then on, this publication was periodically sent to IHF members. It rapidly become *the* source of information for the community. These publications were financed by various pharmaceutical companies, and usually had the back cover advertising the latest AFC marketed by the financing company.

⁴² R.ANDERSON, M.BURY, *Living with chronic illness*, London, 1988, 6.

⁴³ The existence of this phenomenon (which, as far as the present writer knows, has never been analyzed -- at least not in Italy) emerged in the course of an interview to Umberto Randi, the IHF Secretary.

charge to pharmacies, with the Treasury totally covering their cost⁴⁴. IHF played a prominent role in achieving these results⁴⁵.

In the early '80s, the efforts to make effective what in the previous decade had been the IHF's slogan had succeeded⁴⁶. The majority of Italian hemophiliacs could (or would have soon be able to) get "AFC delivery on the home threshold"⁴⁷. In 1978 an estimate in a study presented at the fourth triennial congress of IHF calculated that Italian hemophiliacs consumed 26,500,000 I.U. of factor VIII. Yet, no official and precise surveys had been conducted on the Italian bleeding disorder population. The incidence of hemophilia in Italy was estimated at a ratio of 15-20 patients per 100,000 male births.

Therefore, the total number ranged from 3750 to 5000 hemophiliac subjects of a national male population of approximately 25,000,000⁴⁸. In 1983 the average consumption of a single hemophiliac did not reach 20.000 I.U./year. Compared to foreign data, this quantity was deemed insufficient by experts: according to them the Italian hemophiliac was still under-treated⁴⁹.

Yet clearly, a vein of "therapeutic enthusiasm" had pervaded both doctors and patients.

The Unheeded Lesson: The Trilergan Case

Beside the triumphs of AFC in the treatment of hemophilia, the '70s saw the first hints of dangers implied by the use of blood products manufactured from large pools of donors.

The discovery of the hepatitis B antigen⁵⁰ -- in the mid '60s -- was the first step toward the screening of blood for a virus recognized as a cause of iatrogenic disease in transfused patients since the '40s⁵¹. From 1969 onwards, the Australia antigen (HBsAG) screening techniques evolved rapidly⁵². With regards to the risk of hepatitis-tainted blood,

⁴⁴ DM January 17, 1975 and DM August 2, 1975.

⁴⁵ IHF promoted an intense congressional activity during the '70s.

⁴⁶ P.M.MANNUCCI, L'emofilia curata a domicilio [Hemophilia treated at home], in CDS, May 1, 1975, advocating the adoption of treatment for hemophiliacs at home.

⁴⁷ Self-treatment techniques were illustrated to hemophiliacs by the IHF handbooks. Concerning the risks of home self-treatment one of this companion explained in 1976: "...the AFC administration is a substitutive therapy, that is, it is not an extraneous medication administered to the human body, but rather a factor obtained by human blood, which, though normally present, is absent or not sufficient in the hemophiliac's body. Therefore, AFC administration may never have contraindications (except in presence of inhibitors), nor is the manifestation of harmful effects by overdose possible. This latter aspect must be stressed, since physicians often are fearful of administering excessive doses of AFC to patients: *more is always better than less.*" [italics in the original], IHF Manualetto n.4, 1976, 17.

⁴⁸ GHESSE, DE BIASI, Disponibilità e utilizzazione dei concentrati emofilici in Italia, 1978, Milan.

⁴⁹ F.RODEGHIERO, Terapia domiciliare dell'emofilia: aspetti medici ed organizzativi, in Atti del convegno "La terapia domiciliare dell'emofilia: esempio di medicina preventiva e riabilitativa", Vicenza - 28 May 1983, 26.

⁵⁰ G.DE STASIO, Il rischio trasfusionale, 1995, Milan, 2, quoting B.S.BLUNBERG ET AL., Multiple antigenic specificities of serum lypoproteins detected with sera of transfused patients, in *Vox sanguinis*, 1964, 9, 128; id., Hepatitis and leukemia: their relation to Australia Antigen, in *Bull. NY acad. med.*, 1968, 44, 1566.

⁵¹ MORGAN ET AL., Jaundice following administration of human blood products, in *Brit. Med. J.*, 1943, 1, 750; L.B.SEEF ET AL., A serological follow-up of the 1942 epidemic of post-vaccination hepatitis in the United States army, in *N. Eng. J. Med.* 316, 1987, 965.

⁵² Screening methods advanced and improved remarkably in the lapse of a few years: the gel diffusion technique (1968); the elettrosineresys and blood agglutination (1970); the radioimmunologic technique or RIA (1972), DE STASIO, quoted above, 4.

the Italian blood collection regulations issued in 1971 envisaged only a general medical interview. Donors with a medical history of jaundice were excluded from donation. But no testing was legally imposed or even suggested.

One may well wonder how the Italian ministerial decision-making interacted with scientific evidence concerning improved techniques of HBsAG screening, and how the implementation of the latter was institutionally handled.

The first trace of institutional warning appeared in a *Circolare*, a ministerial communication, in 1971⁵³. It outlined that, since several pharmaceutical industries had already started marketing the necessary reagents, the systematic introduction of the screening of blood to be transfused could no longer be postponed and suggested that all transfusion centers should introduce screening. A long institutional silence followed this first 'soft' and general sign of alert, until a further communication in 1975⁵⁴ specified the methods to be applied in HBsAG blood screening.

Meanwhile, a first case of mass contamination from blood product had occurred. In 1974, a considerable number (estimates advanced by the press at the time indicated between 150 and 500 cases⁵⁵) of users of Trilergan, an anti-allergenic drug, developed hepatitis B a few weeks after administration. The drug was produced by Crinos, an Italian pharmaceutical company, and contained gamma-globulin provided by an Italian blood derivatives producer, the Istituto Sieroterapico Milanese Serafino Belfanti, which in turn had imported the immunoglobulins from the American company Armour Pharmaceutical⁵⁶.

This first Italian episode of viral contamination through blood products, at that time, went almost unnoticed. Facts were presented as controversial by the press⁵⁷. The Health Ministry, in charge of ordering the immediate seizure of the drug when the first cases were reported, did not act promptly: the seizure was ordered only eight months after the marketing of the drug. No accurate administrative inquiry was ever conducted to determine what had gone wrong in the institutional control system then in place to preserve the viral purity of blood products.

After all, in the mid '70s the risk of viral contamination from blood products could likely be considered an inevitable inconvenience, a possible occurrence⁵⁸. Consequences of hepatitis were deemed serious, but still acceptable if compared to the great therapeutic potential of blood products derived from large pools of donors. Not surprisingly, the Trilergan case rapidly sank from the press headlines into oblivion.

⁵³ Health Ministry Circolare 30 June 1971, n.1188. One should be aware that a *Circolare* is not legally binding *per se*. Conceived to be an internal communication between superior and inferior administrative bodies, a *Circolare* may express an order, which applies only to the administrative office at which it is effectively directed and not to third parties. This explains why the publication of a *Circolare* in the Italian Legal Bulletin is not made compulsory by law. The very same feature suggests that, in terms of rule-making, a *Circolare* is not the most suitable legal vehicle for ensuring uniform and prompt implementation of mandatory measures, especially when these are addressed to a host of health facilities located throughout the country and embedded in a highly hierarchized administrative system.

⁵⁴ Health Ministry Circolare 9 December 1975, n.99.

⁵⁵ P.GUZZETTI, E il controllo? Dopo [Controls when? Afterwards], in *Panorama* 16 October 1975.

⁵⁶ For a medical discussion of the Trilergan case see F.L.PETRILLI ET AL., Hepatitis B in subjects treated with a drug containing immunoglobulins, in *The journal of infectious diseases*, 1977, 2:95.

⁵⁷ CDS 24 April 1975.

⁵⁸ P.M.MANNUCCI ET AL., Asymptomatic liver disease in hemophiliacs, in *J.clin.Path.*, 1975, 28,620.

The task of shedding light on what had occurred rested on the courts after that several lawsuits had been brought against Crinos, the final distributor of the drug, between 1975 and 1978. From a legal point of view, as we shall see when examining the pending controversies aroused by the HIV blood contamination, the Trilergeran litigation established crucial juridical principles, holding legally accountable both the Italian pharmaceutical companies and the American supplier of the hepatitis-tainted gammaglobulins.

From the policy-makers point of view, however, a prompt analysis of the 1974 events should have made it clear to the Italian Health Authorities that the existing controls prescribed for blood products safety were merely formalities. The Trilergeran affair clearly pointed out this deficiency with specific regard to imported raw blood components.

The records of the legal proceedings many years later revealed that, although the Italian importer had followed the ministerial prescriptions then in force, the American gamma-globulin had proved to be infected. It was further revealed that, concerning their HBsAg testing, the Italian importer had duly relied on the FDA certification produced by Armour pharmaceuticals.

These findings should have been a call for a careful review of the entire control system in force at that time to ensure the viral safety of blood products. Future regulations should have been conceived in order to guarantee that each batch of blood derivatives was effectively tested. But nobody at the time realized the importance of modifying the “philosophy” of the regulations on blood products safety.

Three years after the Trilergeran mass contamination case, the Health Ministry finally drew its conclusions. Once again, as proof that the problem of viral safety of blood products was still regarded as secondary by the supervising public authority, the measures to be enacted were issued by means of a *Circolare*⁵⁹. Transfusion centers and pharmaceutical industries were required to test each single blood donation (regardless of its therapeutic use) for HBsAg by means of a third generation method, discarding blood tested positive.

It was also imposed that long-preservation blood derivatives should be manufactured only from tested blood, and that each batch of final blood products had to be re-tested. Authorization for the marketing of the products would be issued only upon communication of these results to the Health Ministry. Records of these had to be kept by the importing company in order to ensure future documentation of the tests performed. Moreover, importation of blood products was to be permitted only from countries whose legislation ensured the same level of safety as in Italy. The importing companies were required to certify this condition not only by obtaining a formal declaration from the exporting country’s Health Authority, but also by attaching copy of the blood safety regulations enforced in the exporting foreign country.

These provisions, although late in coming, could be considered effective in combating the risk of hepatitis B contamination of the Italian supply of blood products. Furthermore, looking beyond hepatitis, their severe rationale could have been applied in the future to new viral agents. Instead they were conceived in order to apply solely to the case of hepatitis B.

Had these regulations been issued with more foresight, and within a more flexible legal framework, the same regulatory pattern would have been readily available in the

⁵⁹ Health Ministry *Circolare* 24 July 1978, n.68.

event a new virus was to become a source of safety concern. The tragic events of the following decade would confirm the lack of such a flexible, general regulatory scheme.

Clearly, the approach followed by the Italian Health Ministry in dealing with blood viral safety during the '70s indicates that blood safety policy was still regarded as a by-product of bureaucracy rather than institutional decision-making.

The Advent of HIV: The Years of Uncertainty (1982-84)

In Italy, the first cases of *Pneumocystis carinii pneumonis* and Kaposi's sarcoma were reported in 1982 among gay man returning from foreign countries. The first case officially classified as AIDS involved an intravenous drug user from Milan and occurred in the first semester of 1984; at the end of that semester a total of 10 cases had been reported in the country⁶⁰.

In the summer of 1983, a few months after the first scientific description of the HIV retrovirus (then referred to as LAV/HLTV-III), the Italian Health Ministry informed the regional health authorities about the characteristics of the new disease, and instructed that any ascertained or even suspected case should be reported to the *Istituto Superiore di Sanità* (ISS), the Italian National Health Institute⁶¹. This first institutional sign of alert for the new disease suggested that its viral etiology might be similar to that of hepatitis B. No mention, though, was made to the possibility that HIV could be transmitted by blood.

In May 1983, a periodical newsletter by the ISS had already published an informative article on AIDS. It reported the American data on AIDS in hemophiliac patients and focused on the causal link between the use of commercial AFC made from large pools of donors and the disease. The article clearly stressed that recipients of cryoprecipitates faced a lower risk of viral contamination, due to the fact that these blood products were obtained from small pools of donors⁶².

In June, the Committee of Ministers of the Council of Europe met in Strasbourg in order to adopt a common resolution addressed to prevent AIDS transmission from infected blood donors. The Italian Health Ministry was institutionally represented. Its representatives participated in the drafting of the European Recommendation, which, although not legally binding for the member states, openly spoke of the serious risk of AIDS contamination to which blood and blood product recipients were exposed. The institutional *caveat* addressed on June 24, 1983 to the national health authorities of the member-states could not be more straightforward:

“to avoid wherever possible the use of coagulation factor products prepared from large plasma pools: this is especially important for those countries where self-sufficiency in the production of such products has not yet been achieved;

to inform attending physicians and selected recipients, such as hemophiliacs, of the potential health hazards of hemoteraphy and the possibilities of minimizing these risks;

to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups will refrain from donating (an example of an information leaflet for donors is appended); to pursue rapid

⁶⁰ G.REZZA, *Epidemiologia dell'AIDS in Italia*, in *Il libro italiano dell'AIDS*, Milan, 1994, 3.

⁶¹ Health Ministry *Circolare* 3 August 1983 n.64; see I.SERAFIN, *La normativa italiana sull'AIDS*, *ibid.*, 11.

⁶² ISIS, *Medicina nel mondo* 19/83, n.19, 14 May 1983, 11-12.

and full implementation of recommendations No. R (80) 5 and No. R (81) 14.”⁶³.

A research through the Italian legal bulletin leads to the paradoxical discovery that, in that same June of 1983, the Health Ministry went to the length of issuing detailed regulations for the production, trade and use of cow and pig plasma proteins⁶⁴. It is not less paradoxical to note that Italy remains today one of the few countries among the industrialized nations where an “official history” of HIV blood contamination has not been compiled by a government commission. Accordingly, why the Italian Health Ministry bureaucracy ignored the European Recommendation when the first institutional information about the disease was released in August 1983 remains a mystery to this day⁶⁵. Although the text of the recommendation was promptly translated and published by an Italian specialized journal for blood transfusion physicians⁶⁶, the significance and the magnitude of the warning would have been clearly different if it had been institutionally endorsed in an official communication of the Health Ministry.

Back in 1983, the conclusions reached the previous year at the Focus Panel on blood and plasma national adequacy⁶⁷ had brought the Health ministry to appoint a commission of experts in charge of elaborating a five-year national blood plan. In December, this plan was on the desk of the Health Minister. The final report to be spread among blood system operators contained the statement “(B)lood transfusion may transmit diseases (Hepatitis, AIDS)”⁶⁸. But, once again, this concept languished in the ministerial in-tray, following the destiny of the national blood plan, which was never enacted.

A year had silently elapsed from the first institutional information about HIV in August 1983, before the Ministry issued a second host of recommendations addressed, this time, specifically to health care workers. Further to a first set of measures to control the spread of AIDS among intravenous drug users and instructions concerning the epidemiological surveillance of the disease, the Ministry clearly stressed the risk of HIV transmission by accidental blood contact with patients.

For some strange reason, the prophylactic guidelines (freshly issued at that time) by WHO in order to prevent this type of risk were in this case promptly followed by the bureaucrats of the Italian Health Ministry⁶⁹. And yet, as for the Strasbourg

⁶³ 23 June 1983: Ministries Committee of the European Council Recommendation n. R (83) 8, in *Recueil International de Législation Sanitaire* (hereinafter: RILS) 35.1, 1984, 54. Of the two recommendations mentioned in the text, the R (80) 5 (*Ibid.* 33.1, 1982, 18) recommended the implementation of plasmapheresis obtained from voluntary blood donations and spelled out the risk of viral infections from pools composed of plasma from different regions. It gave detailed instructions on the use of antihemophilic concentrates and recommended that member states should create national registers of coagulopathic subjects. Recommendation R (81) 14 (*Ibid.* 33.2, 1982, 277) dealt with the general prevention of infectious diseases transmitted by the trade in blood and blood products among countries, and urged member-states to consider the epidemiological situation of the country of origin when importing blood and blood products.

⁶⁴ See DM 9 June 1983 (in GU 25 June 1983, n.173).

⁶⁵ Sabotaging recommended solutions is seen as a possible outcome of the difficult interaction between members of a bureaucratic organization and external advisors, see the interesting analysis of H.S.BAUM, *The invisible bureaucracy. The unconscious in organizational problem solving*, New York - Oxford, 1987, 145.

⁶⁶ *Il Servizio Trasfusionale*, 12, 1983:4.

⁶⁷ First Focus Panel on the National Blood Plan, quoted above, sub note 3.

⁶⁸ *Proposta di piano sangue quinquennale*, Ministero della Sanità - Centro Studi, December 1983.

⁶⁹ Health Ministry *Circolare* 25 June 1984, n.48 and 25 August 1984, n.65 (in RILS, 37.3, 1986, 582-3).

recommendations, one may infer that the international guidelines emanating from Geneva were not legally binding either for the Italian government.

The preceding facts may allow for a first conclusion. When evaluating with hindsight the behavior of the Italian health institutions in the two years following the CDC report of July 1982, the risk of underrating the uncertainties of the time should be born in mind. Nevertheless, in this retrospective evaluation two behavioral profiles may be highlighted. Clearly, the uncertainty issue (accompanied by the then existing clash between opposing scientific, political and also productive opinions) should not be forgotten when laying blame on institutions for the belated introduction of countermeasures concerning surrogate testing, donors exclusion and use of heated AFC.

But the “uncertainty” scapegoat cannot be raised as easily when one comes to the analysis of a second behavioral profile: the role played by institutional decision-makers in spreading information about the existence of a risk within the blood system and among its operators⁷⁰. With reference to this lack of information, the failure of the Italian Health Ministry appears striking in retrospect.

In the absence of institutional action, information was a scarce resource, left to scientific initiatives like the one that an Austrian AFC producer undertook in March 1983, through a note published in a newsletter periodically sent home to Italian hemophiliacs:

“...Since the MMWR report of July 1982, less than 10 cases of AIDS in hemophiliacs have been described in USA. The correlation lets us suppose that the pathology may be transmitted not only via homosexual intercourse, or via intravenous drug use, but also via blood. Homosexuals are a significant share of the plasmapheresis donors in the big American cities. Infected plasma from these donors may therefore contaminate the pool from which AFC are obtained. Among the several proposals made in order to reduce the risk of transmitting this mysterious virus, there is donor exclusion of groups at risk and the possibility to have as soon as possible AFC treated against blood transmissible viruses. Moreover, medical literature (quoting: *Hemophilia Foundation passes AIDS resolution*, in *News briefs*, November/December 1982 Vol.5 n.11; H.STRAWCZYNSKY, *Aids: a report*, in *Hemophilia today*, January 1983, Vol. 20 n.1) is unanimous in suggesting no modification to the current therapeutic protocols for hemophiliacs, given the very low AIDS incidence among these patients and the hemorrhagic risks which would be increased by an insufficient substitutive therapy. It is important to stress that concentrates distributed by Immuno in Europe are exclusively manufactured in European Plasmapheresis Centers; plasma collected at Immuno’s Plasmapheresis Centers in the USA is fractionated and distributed only in the USA. At any rate, we believe it proper to disclose that Immuno, in its constant commitment to research, has developed an original method (not based on UV radiation or heat treatment) for the production of concentrates free from contaminating viruses; batches treated with this method are already being marketed.”⁷¹

⁷⁰ “It is very much in the spirit of cultural theory to threaten the institutions themselves as the monitors which determine what is going to count as information”, M.DOUGLAS, *Risk and blame*, quoted above, 18-19.

⁷¹ Medical-scientific Direction of Immuno, *La sindrome da immunodeficienza acquisita -- dalla Immuno S.p.a.*, in *Ex*, n.3 March 1983).

Added to this “dynamism” of pharmaceutical companies in spreading information about the new “American” disease⁷², an Italian research group published at the beginning of 1984 one of the first scientific articles in medical literature to evaluate in hemophiliac patients the association between abnormalities of lymphocyte subset and the quantity of annual consumption of AFC derived from American plasma⁷³. This article concluded:

“(A)bnormal lymphocyte subpopulations *per se* cannot yet be used for diagnostic evidence of AIDS or its prodrome; only by longitudinal studies of asymptomatic hemophiliacs with abnormal values can the relevance of such tests to AIDS risk be established. Therefore, we cannot recommend using less than 20,000 U/yr. in an attempt to prevent AIDS solely on the basis of these data. We continue our present policy of giving all the factor they need, on demand, for treatment of hemorrhages and elective surgery. However, we avoid long term prophylaxis in an attempt to prevent all hemorrhage because there is no proof that such prophylaxis results in better prevention of hemophiliac arthropathy, while it does result in much larger concentrate consumption.”⁷⁴

In the course of 1984 the Italian scientific community organized several international conferences in order to follow the evolution of scientific knowledge about AIDS. In May, Luis Aledort presented a report on “AIDS, hemophilia, blood transfusions and blood derivatives” at an international conference on AIDS held in Sardinia⁷⁵; in October, at an international symposium held in Milan⁷⁶, Bruce Evatt of the CDC reported about the situation in USA, whereas Adrian Bloom from Cardiff University spoke about “AIDS in hemophiliacs in Europe”.

The antennae were up and something was about to happen.

⁷² Many years later, H.J.Eibl, Director of Immuno, when interviewed regarding the relationship between high incidences of HIV infection among hemophiliacs and the degree of import from the USA in the early eighties, will explain: “Nobody knew anything about the HIV infections in the late seventies and early eighties. So this contamination could not be avoided. It is true that in countries like Finland with almost no import of plasma products the incidence of HIV infection among hemophiliacs was low. On the other hand, countries like France and Switzerland had a high incidence, in spite of the fact that they imported almost no American products. So it is the epidemiological situation of a country which explains the incidence of HIV infection more than the degree of self-sufficiency. You cannot blame industry for not reacting in time. Within two years, we had techniques to screen donors and methods to inactivate the virus. Seldom have innovations been carried out so fast.” In P.J.HAGEN, Blood transfusion in Europe: a white paper, Strasbourg, 1993, 26.

⁷³ P.M.MANNUCCI ET AL., Abnormalities of Lymphocyte subset are correlated with concentrate consumption in asymptomatic Italian hemophiliacs treated with concentrates made from American plasma, in Am.J.Hemat. 17:167 (1984).

⁷⁴ Ibid., 175. On how scientists take decisions in a bounded rationality setting and on the dominant role of the decision-maker’s values and interests in the final choice, R.N.GIERE, Spiegare la scienza, Bologna, 1996, 257 ss. [id., Explaining science. A cognitive approach., Chicago - London, 1988].

⁷⁵ International meeting on causes, pathogenesis, management and treatment of AIDS and related conditions, held in Cagliari, 1-3 May 1984. Curiously, the cover of the conference’s leaflet presented a world globe showing only two islands, Haiti and Sardinia, linked by a red line.

⁷⁶ AIDS: research status and epidemiology, fifth annual conference of the IHF’s Medical Scientific Committee, held in Milan, 1-2 October 1984.

Information Vs. Risk Perception

At the end of 1984 the Italian health authorities had still not taken an official position toward blood safety from HIV: neither from an informative point of view, nor in a practical way, through the exclusion of donors at risk. Unobserved, the first decree authorizing the marketing of a dry-heated factor VIII concentrate produced by Immuno appeared in the legal bulletin in December 1984. Other brands this authorization within March 1985, whereas for three brands that marketed heated factor IX, authorizations were released, respectively, at the end of March, in April and December 1985.

Yet, this bureaucratic clearance still lacked institutional action addressed to facilitate the distribution and consumption of these safer AFC among Italian hemophiliacs. The price of these new pharmaceutical specialties far outweighed that of the untreated ones (on average the former product cost five times more). Switching to the new product not only entailed a financial burden for hospitals and pharmacy administrators, but the temptation to liquidate the left over stock could be predicted. Not to mention that hemophiliacs living far from health facilities had the habit of storing large personal supplies of AFC in their home refrigerators. Prompt and precise information became crucial, given the ongoing lack of a legal ban on untreated concentrates. In this context, hemophiliacs could only rely upon themselves.

In March 1985, members of IHF received in their mailbox the therapeutic handbook edited periodically by the Scientific Committee of the *Fondazione*. The handbook expressed concern over the first dramatic findings in the United States. It stated, however, that the HIV retrovirus rarely developed into full-blown AIDS. The data sought to minimize the fear:

“(O)nly one hemophiliac in 1,000/2,000 has full-blown AIDS in the USA and other European countries; on the other hand, cases among non-hemophiliacs in Italy amount to no more than 20/30, as compared with 200/300 in other European countries similar in size to Italy, like England, France and Germany. It would seem, then, that the Italian hemophiliac has greater defensive powers and it is to be hoped that this tendency will be confirmed!”.

To the question “(W)hat can the hemophiliac do to protect himself from AIDS?” the handbook answered:

“[The hemophiliac] may, or will soon be able to, screen his/her serum for LAV/HTLV III by means of commercial kits that will be available in a few months time and are already available in some Centers. It must be recognized, however, that it is still not clear whether the presence of antibodies, detected in about half of the hemophiliac treated with more than 20.000 I.U. in our Center, signals the actual presence of the virus in the blood or whether it is rather a sign of a remote contact or, maybe, protection...”.

To the question “(W)hat are ‘treated’ concentrates?”, the pamphlet reported that the first results obtained using dry-heat or high-pressure methods to inactivate the AIDS retrovirus were very encouraging⁷⁷. It ended:

“(O)n the basis of this data we can give a set of important messages to the Italian hemophiliac: AIDS has still not appeared in Italy; the risk of new concentrates is lower than old ones, or may be even nil. Therefore there is no reason to abandon, reduce or, at any rate, change the treatment programs and the concentrate dosages that have proved able to transform the hemophiliac condition from a state of dependence and permanent frustration to a condition of autonomy and free expression of individual capacity”⁷⁸.

In that spring, the same message appeared again in the IHF newsletter, this time with a firm reprimand against the “unjustified alarm” provoked in the hemophilia community by the news about the presumed case of a hemophiliac, who turned out not to have AIDS⁷⁹.

The Abbot test for HIV was approved by the FDA in March, and the use of the kit was authorized by the Italian Health Ministry the following month. At the end of May, IHF organized a press conference in Milan. The imminent wholesale availability of the Elisa test was announced and hemophiliacs were publicly invited to use only dry-heat treated AFC, those labeled with a green stripe on the packet as the executive secretary of IHF specified. At the same time Mannucci, director of the Scientific Committee of IHF, restated that the dimension of the contamination monitored at the time among the Italian bleeding disorder community was small. Again, emphasis was put on the impression that AIDS incidence in Italy was low when compared to other countries and that, for those hemophiliacs who had tested positive to HTLV III antibodies, the contact with the virus was not a death sentence, since only one out of 1000 or 2000 of those positive hemophiliacs had developed full blown AIDS in the USA⁸⁰.

With hindsight this message reveals its spirit: warning and reassuring, inviting hemophiliacs to undergo a closer follow-up of their antibody status and stating that the test positive results did not mean that the deadly disease would manifest itself. A picture of the uncertainty of the time, indeed, framed by an innermost desire to hold on to optimism, to not surrender. After fifteen years of relentless improvements in the treatment of hemophilia, it was hard to dismiss a well-rooted melioristic attitude. Spread on the eve of what was then viewed as the end of the risk’s state (the massive adoption of treated AFC), these declarations may appear today as a by-product of the “scientific magic”. That

⁷⁷ P.M.MANNUCCI, L.MONTAGNIER ET AL., Absence of antibodies to AIDS virus in hemophiliacs treated with heat-treated factor VIII concentrate, in *Lancet*, 2 February 1985.

⁷⁸ All excerpts translated with emphasis in the original, see, *Fondazione Italiana dell’Emofilia*, *Manualetto*, n.8/scheda 2, February 1985.

⁷⁹ *Rapporto annuale del comitato medico scientifico della Fondazione Italiana dell’Emofilia*, in *Tra noi*, n.3, spring 1985.

⁸⁰ The conference had a vast echo in the press at the time: see S.GIACOMONI, *Contro l’Aids arriva “Elisa” un nuovo test per le trasfusioni* [Elisa arrives to fight AIDS, a new transfusion test], in *La Repubblica*, 31 May 1985; P.MASTROLONARDO, *Milano decide: test per i donatori* [Milan decides: test for donors], in *Il Secolo XIX*, 31 May 1985; AIDS, *Ricercatori milanesi: “immotivato il panico”* [AIDS, Milan researchers: “unmotivated panic”], in *Il Manifesto*, 31 May 1985; *Nuovi controlli nelle trasfusioni per limitare i rischi* [New controls on transfusions to limit the risks], *CDS* 11 June 1985.

is, “[that attitude which] helps physicians to face problems of uncertainty, therapeutic limitation and meaning by ritualizing optimism ...”⁸¹.

Government Action

Finally, on July 17, 1985, the Health Ministry issued the *Circolare* n.28, which (with the clarifications that will soon be given) can be considered the first legal source marking the introduction of basic precautions against the HIV contamination of blood and blood products in Italy. Under the label “survey and prophylaxis of the LAV/HTLV III virus”, this ministerial communication provided for the testing of blood donors in order to detect the presence of the virus’s antibodies and recommended, according to the organizational capacities of each center, that the test be introduced as soon as possible, screening all donations. It also generally recommended that groups at risk should not be allowed to donate blood, although it did not suggest exclusion from donation for individuals only suspected of belonging to high-risk groups. The *Circolare* was also sent to pharmaceutical companies, stressing the need to use pasteurization in the production process. This communication, which never appeared in the legal bulletin and was not legally binding, did not impose, but only recommended. Nevertheless, at present in Italy July 17,1985 is often emphatically stressed as the date of operative enforcement of all necessary measures to reduce the risk of HIV-blood contamination.

More realistically, tracing the chronology of regulatory action lay down by the Italian Health Authority in order to ensure the safety of blood supply and blood products from HIV, it must be recognized that a clear legal obligation in this sense was not issued until promulgation of the Decree-law April 29, 1987, 166⁸², as later specified by the Ministerial Decree January 15, 1988, n.14⁸³. Prior to these dates, one only finds a

⁸¹ R.C.FOX, *The human condition of health professionals*, in *Essays in medical sociology*, 1988, New Jersey, 581. The author goes on: “(F)irst it is the tendency of medical practitioners to favor demonstrably vigorous ways to treat patients, and their accentuate-the-positive inclination to be staunchly hopeful and tenaciously confident about the success of their active intervention - even when, and often especially when, a positive outcome is unlikely. Trying hard to “do something” effective about a serious medical problem can have a “self-fulfilling prophecy-like impact on health professionals, patients, and patients’ families alike. Particularly in an energetically melioristic culture like our own, with its “we shall overcome” outlook, it can encourage all concerned to endure, persist, and continue to believe, in ways that can contribute to the stabilization of a patient’s condition, to its improvement, and beyond that, to his or her recovery”.

⁸² In GU 31 October 1987, n.255, later converted into Law 29 December 1987 (in case of emergency or necessity the Italian Government has the power to issue a Decree-law whose provisional measures go into effect immediately. If not converted into law by Parliament within 60 days, the Decree loses all effects and lapses. Frequently, the Government repeatedly re-issues the same Decree-law until agreement is finally reached with Parliament. This practice has become a standard in recent years, with perverse effects on the certainty of the legislation). It was established that the local health facilities had to ensure the HIV screening of all blood units collected, assigning only the units testing negative to direct transfusion or to blood and plasma derivatives production. The same mandatory procedure was prescribed for blood or blood derivatives imported from abroad. The promulgation of technical standards for testing (in this case extremely important) was postponed to a future ministerial decree.

⁸³ In GU 26 January 1988, n.20. All transfusion centers were mandatorily instructed to use anamnestic precautions for HIV in donor selection, excluding the group at risk (injecting drug users, male homosexuals, HIV positive partners, partners of subjects at risk, multi-transfused since 1978). The screening of all donors for HIV was also ordered, adopting a two-pronged test procedure based on methods, authorized in March 1987, by a previous ministerial decree. HIV analysis data had to be recorded in the transfusion center’s registers; these centers were obliged to periodically send a six-month report to the Health Ministry. Concerning blood product precautions, pharmaceutical companies authorized to produce

disparate set of ministerial communications and recommendations on diverse health policy aspects related to the new disease. These notes lacked coordination and, in some cases, were transmitted to regional health authorities by telegram⁸⁴.

If submitted to peer review, this patchwork of regulations depicts the image of fragmented institutional decision-making, stifled by bureaucracy. For instance, with regards to the implementation of treated AFC, the Italian Health Ministry recommended adoption of the dry-heat viral inactivation technique in the July 1985 *Circolare*. But it was only with the next communication of July 1986 that the Ministry mandatorily prescribed that all plasma products should be made from negative-testing single units of plasma, and that pools of production should be subjected to wet-heat treatment⁸⁵. Scientific evidence, in fact, had clearly stated the greater safety ensured by this viral inactivation technique. One would have expected the Health Ministry to act accordingly. That is, to immediately order the withdrawal of all the stocks of concentrates which did not comply with this safer technique then in distribution or stored in hospitals. But this did not happen until the end of May 1988, when a series of *ad hoc* decrees suspended authorization to market dry-heat treated AFC⁸⁶.

According to these official dates, the Italian regulatory response to the risk of HIV contamination for blood and blood products does not reveal a farsighted approach when compared to other national experiences. On the contrary, a closer look brings to light the shortcomings displayed by bureaucratic rule-making, unable to enforce clear legal obligations in the blood system, when this was necessary to ensure the immediate implementation of vital countermeasures as, for instance, HIV screening of blood donors.

This conclusion is confirmed when reviewing the initiatives taken by some regions, which, without awaiting the government's mandatory instructions, immediately acted upon the July 16, 1985 "recommendation". Lombardy, the Italian region most concerned with AIDS because it had the highest rate of cases, banned distribution and

or import plasma or blood derivatives were instructed to use only blood or plasma previously tested for HIV and resulting negative in the manufacturing process, specifying that foreign companies must certify that tests had been carried out with methods authorized by the foreign country's Health Authorities. A viral inactivation method previously authorized by the Health Ministry was to be applied to AFC. The technical directors of pharmaceutical companies had to certify that each batch of products had been individually tested for HIV, and that they were available to exhibit the relative certification upon request.

⁸⁴ Compare the set of communications that Veneto Region health authorities received from the Health Ministry which are listed in the Veneto Region Note 28 August 1986 "HIV infection -- Surveillance and prophylaxis measures". This regional communication shows how individual regional health authorities could, in some cases, be very efficient in informing their health facilities about the measures to be taken against AIDS. The note recommended that, even if no cases had so far been reported of HIV transmission through immunoglobulins, the discovery -- in some batches -- of specific antibodies suggested their use only in case of real necessity and in moderate quantities. To make the warning effective physicians were reminded of their potential civil and criminal liability in cases of haphazard prescription of immunoglobulins (but the rationale of the warning could be extended to transfusions and blood products).

⁸⁵ Health Ministry *Circolare* 16 July 1986, n. 47 (in RILS, 1986, 37:4, 843).

⁸⁶ See the set of decrees of 27 May 1988 (in GU 17 June 1988, n.141). In a note dated 2 June 1988, the by then Director of the Pharmaceutical Service of the Health Ministry, Duilio Poggiolini, stated that one of the withdrawn products lacked any heat treatment. The "clean hands" scandal of 1993 revealed that Poggiolini, who had been the head of the ministerial pharmaceutical department for 20 years, had accumulated a multi-million \$ fortune divided among Swiss bank accounts and Picasso paintings as personal profits from corruption (see, Tesoro in quadri nelle case romane di Poggiolini [A treasure in paintings in the Roman mansions of Poggiolini], in L'Unità, 9 November 1993). Among the many penal proceedings against the former ministerial director, also pending is an investigation carried out by the Naples criminal prosecutor into the above mentioned facts.

administration of untreated AFC on July 31, 1985⁸⁷, and enacted a detailed set of mandatory measures concerning HIV blood testing the following November⁸⁸.

Body Counts: The “Numbers” of the Italian Contamination

From 1985 onwards, epidemiological data began to clear the uncertainty. In discussing these data, of course, a distinction should be made between the different classes of subjects exposed to HIV contamination: hemophiliacs and transfusion recipients.

A) As regards the former, it should be considered that, until 1988, Italy lacked a national, official census of the population with bleeding disorders. From the ‘70s to the early ‘80s, the number of Italian hemophiliacs could greatly vary, according to the source and the context in which the numbers were quoted. In some cases, as when in the early ‘70s the number needed to draw political attention to the disease, the Italian bleeding disorder community was said to number up to 10.000 Italians. A few years later, more realistic estimates based on variable rates of incidence of the bleeding disorders among the general population reduced these figures to approximately 4000 subjects.

Only in 1983 the IHF and the Milan hemophilia center began to carry out an accurate national survey, with the specific purpose of evaluating the prevalence and characteristics of HIV infection in Italian hemophiliacs. The other Italian centers were invited to provide data, according to the parameters set by the center promoting the initiative. The results of this survey (which were not complete, since not all the centers had furnished data) were officially published by ISS as the first national report on congenital bleeding disorders in 1988. Simultaneously, these data were presented by the survey’s authors to the international scientific community, comparing them to similar data reported in France and Germany.

* ⁸⁹	Surveyed	Hemophilia A				Hemophilia B	
		<i>AIDS cases</i>	<i>HIV cases</i>	<i>AIDS cases</i>	<i>HIV cases</i>	<i>AIDS cases</i>	<i>HIV cases</i>
Germany	2,476	148 (6.0%)	1,172 (47.4%)	131 (6.1%)	1,024 (47.6%)	17 (5.2%)	148 (45.6%)
France	2,445	58 (2.4%)	1,038 (42.3%)	40 (1.9%)	903 (36.9%)	18 (4.6%)	136 (35.0%)
Italy	2,792	57 (2.0%)	637 (22.8%)	36 (2.2%)	476 (28.7%)	20 (6.4%)	138 (44.1%)

Without doubt, these data were comparatively striking: although it became clear that Italy had not been saved from the international tragedy (637 Italian hemophiliacs had been found HIV-positive), the global rate of contamination (22.8%) appeared far lower than the rates displayed by the two European countries object of the comparison. Regarding Germany, where patients were treated with the same American-plasma-derived AFC as in Italy, this difference was explained by the larger doses of factor VIII administered to German hemophiliacs in the early ‘80s, when most infections had

⁸⁷ Another Northern region, Emilia-Romagna, did the same in September.

⁸⁸ Regional Plan for the fight against AIDS, 22 November 1985 (in Bull. Lombardy Region, n.3, 1986).

⁸⁹ Table reported in A.GRINGERI, P.M.MANNUCCI ET AL., National survey of Human Immunodeficiency Virus infection in Italian hemophiliacs: 1983-1987, in La ricerca Clin. Lab. 18: 275-280 (1988). The study also reported that the first cases of AIDS had occurred in 1984, when Pneumocystis carinii pneumonia and Kaposi’s sarcoma were diagnosed in two patients with no risk factors other than hemophilia, even though -- in 1983 -- 14 patients had been diagnosed as ARC.

occurred (84,000 I.U./patient/yr. vs. 25,000 in Italy). Regarding France, where the average use of AFC had been slightly lower than in Italy (22,000 I.U./patient/yr.), the study reported that beyond the Alps AFC was produced from domestic plasma, without being able to provide further explanations (but, at the time, the French scandal had not yet erupted).

Upon closer observation, though, this comparative analysis casts a doubt. The Italian number of patients surveyed and reported in the table comprised 650 subjects affected by von Willebrand disease and 171 classified as “others”⁹⁰. German and French data instead referred only to patients with hemophilia A and B. In fact, while for these two countries the sum of the disaggregated data reporting HIV infection for different types of hemophilia corresponds to the total number reported in the first column of the table above, this is not true for Italy. The conclusion then appears to be that the compared data were not homogeneous. In order to avoid the danger of underestimation due to the disparity of sources, it seems then methodologically appropriate to make reference to data relating only to hemophiliacs (factor VIII and IX deficient).

In assessing the Italian dimension of the hemophiliacs contamination, the source which is most likely to illustrate its real magnitude is the 1990 national survey of the bleeding disorder population. In fact, examination of more recent surveys would again entail the risk of underestimation, due to the progressive inclusion in these statistics of hemophiliac children born when the risk of contamination was definitively over (from 1987 onwards). The 1990 survey counted a total number of 2839 hemophiliacs in 36 of the 39 Italian centers (2394 A and 445 B). Of those, 2388 (1993 A and 395 B) had been tested for HIV.

	Hemophiliac (A+B)	Hem. A (factor VIII)	Hem. B (factor IX)
Patients surveyed	2839	2394	445
Tested for HIV	2388	1993	395
HIV POSITIVE	719	533	186
% of tested patients HIV positive	30.10	26.75	47.08

Source: Istituto Superiore di Sanità, Registro nazionale delle coagulopatie congenite in Italia. Rapporto 1990, Rome, 1991.

Overall, including VWD and other’s patients, the 1990 survey registered a total of 768 subjects with various bleeding disorders testing HIV positive. This number grew to 820 three years later and has been at a standstill ever since⁹¹.

Clearly, the data just presented state that the phenomenon of Italian contamination was still of lesser incidence compared to other industrialized nations. Was this a consequence of Italian “farsighted” measures taken during the years of contamination? According to our attempt at reconstructing the events, the answer should be definitely negative. One explanation for the lower Italian rate of contamination may be the “lucky” circumstance of a less intense average consumption of AFC. In fact, according to the data of the 1990 survey, the rate of contamination of severe (A+B) hemophiliacs (those

⁹⁰ Ibid., 278.

⁹¹ Istituto Superiore Sanità, Registro nazionale delle coagulopatie congenite in Italia. Rapporto 1993, Rome, 1994.

seemingly treated with more than 40,000 I.U./yr.) rises to 40.07%, with a disaggregated rate of 36.8% for factor VIII and a striking 56.7% for factor IX recipients.

This conclusion remains a possibility, however, since to date neither experts nor institutional inquires have attempted to explain this Italian epidemiological anomaly. Taking for granted that treatment protocols for factor VIII and factor IX deficiency were similar throughout the world, why had this abnormally higher level of contamination occurred among Italians affected by hemophilia B? Does one need to assume that the lucky factor of moderate consumption was valid only for factor VIII recipients? Were there significant differences due to the fact that factor IX AFC used in Italy was supplied only by certain specific pharmaceutical companies?

Possibly, the search for truth in the saga of the Italian hemophiliac contamination had ended even before it began, when those involved acquired a relative sense of relief by comparing the Italian situation to that of other countries. This may explain why so far nobody in Italy has felt the political necessity to pierce the veil of fatalism dropped on the circumstances of hemophiliac contamination, by shedding light on the quantities and the commercial sources of the AFC consumed in the first half of the '80s by Italian hemophiliacs⁹².

B) Data on the transfusion recipients' contamination are far more difficult to deduce from official reports than those concerning hemophiliacs. Whereas it is quite simple to calculate national figures for transfusion-related AIDS cases from the general epidemiological tables drawn up trimestrally by ISS on the basis of the compulsory notification system⁹³, the key data (i.e.: the number of recipients testing HIV positive) can only be estimated.

Indeed, the Health Ministry encountered organizational problems in carrying out a general and systematic "look-back" program for transfusion recipients at risk of HIV contamination in Italy⁹⁴. Such a program, based on the data on HIV cases obtained by means of the mandatory notification system, would have ascertained whether subjects detected as HIV positive had donated blood and, if so, it would have identified the (still unaware) recipients.

Instead, more limited look-back programs had been conducted by ISS starting from transfusion-related AIDS cases signaled by the general notification system, with the twofold aim of identifying donors who unconsciously had transmitted the virus, and, eventually, identifying recipients of infected blood from these donors. But the main goal of these programs was to better classify donors at risk so that more precise data could be made available for medical interviews aimed to reduce the window period risk⁹⁵.

⁹² And yet the recent Italian parliamentary history shows how frequently special parliamentary commissions have been appointed to shed light on a various set of events which have marked Italian political affairs in the last twenty years.

⁹³ In Italy the systematic collection of data concerning AIDS cases began in 1982, and was institutionalized in 1984. Starting from 1986, notification of new cases is made compulsory by law. Whereas AIDS cases must be nationally reported to ISS in Rome, the system of notification prescribes that HIV cases must be signaled to the regional health authority. Both the notifications, though not anonymous, are carried on so as to guarantee the non-disclosure of the data, V.FINESCHI, *Segretezza professionale e deontologia medica*, in P.CATTORINI, *AIDS e bioetica*, Milan, 1992, 51.

⁹⁴ DE STASIO, quoted above, 307.

⁹⁵ R.ARCIERI ET AL., *Programma italiano di look-back per l'infezione HIV da emotrasfusione*, in *TS*, 39:6 (1994) 479-84.

Therefore, while the total number of Italian transfusion recipients who developed AIDS stands at 381, as of 30 September 1996⁹⁶, official figures for HIV-contaminated blood recipients are not available. An internal communication of the ISS dated July 1993 reported a provisional estimate of 700 cases⁹⁷, but the real number may likely be double.

Victims' Awareness: How to Perceive a Iatrogenic Defeat?

The risks posed to blood and blood product recipients by what the media initially presented as the gay and intravenous drug user plague went largely unobserved by public opinion. Despite the fact that the Italian media approach to AIDS in the first decade of the epidemic was described as an “informative overdose”⁹⁸, the sensationalism and hype about the “plague of the year 2000” left the issue of blood safety substantially untouched by the media until 1985. In November of that year, one of the leading Italian weekly newsmagazines focused on the problem of implementation of the Elisa testing. It denounced the belated supply of the Elisa test kits to a transfusion center specialized in the treatment of thalassemic children in Sardinia⁹⁹.

The first article, however, to attach institutional blame to the HIV-tainted blood issue appeared in September 1986. It paid particular attention to the risk of HIV-infected immunoglobulins, and emphasized the threat raised by the American “dirty” plasma, stressing that American pharmaceutical companies allegedly used plasma from paid suppliers, recruited in South America, the Caribbean countries and ghettos of the big American cities. The article denounced the great delay of the Italian Government in issuing a national blood plan, which, if implemented in time, would have permitted Italy to be self-sufficient, and to reduce the risk of contamination¹⁰⁰.

What happened in the hemophiliac community when those who were gradually discovering that they tested HIV positive, began to realize what this condition implied? Until 1985, they had received constant reassurances about the low proportion of Italian contamination and the neutral consequences of the presence of HIV antibodies in their blood. Still in that same year, the standard test report on the positive results of the HIV test contained the following statement:

“POSITIVE. This does not absolutely imply that the patient will develop AIDS, but that he/she will face this eventuality in about 10% of the cases, according to current knowledge. It is recommended to repeat this test every 6 months and to consult a physician at the occurrence of the following symptoms (...)”¹⁰¹.

⁹⁶ ISS, Aggiornamento dei casi di AIDS notificati in Italia al 30 settembre 1996, Rome, 9:12 (1996).

⁹⁷ Letter of 7.29.93 by N.Schianaia from ISS (source: Italian Multi-transfused Association).

⁹⁸ This expression sums up the conclusions of a statistical survey on three leading Italian weekly newsmagazines, see M.BACCI, G.BENUCCI, Percezione dell'AIDS e mass-media: indagine sulle caratteristiche dell'informazione attraverso un'analisi della stampa settimanale, in *Rassegna italiana di criminologia*, 1993, 409.

⁹⁹ S.BOERI, *Questione di sangue [Matter of blood]*, in *Panorama* 24 November 1985, 234.

¹⁰⁰ A.BELTRAMINI, G.MILANO, *Se il sangue è sporco [If blood is dirty]*, *Panorama* 28 September 1986, 246.

¹⁰¹ This example of HIV test report was published on a hemophiliac newsletter, *Ex*, 12:8, August 1985.

In the course of 1987, the hemophiliac newsletter began to collect obituary notices. Beside anonymous letters announcing the death of a member of the community, the paper published in June 1987 the news of the death of Frank Schnabel, the heroic President of the World Federation of Hemophilia¹⁰². The awareness of having been exposed to a fatal contamination produced an implosion in the hemophiliacs' willingness to further trust the voice of the scientific experts, which earlier had managed to change their life perspectives. Only by lending an ear to personal testimonies can one capture the sense of betrayal that was being felt within the bleeding disorder community.

The individual reactions to the tragedy overwhelmed the "sense of the community" that hemophiliacs had slowly achieved in fifteen years of successful action. Mixed feelings of rage and hope coexisted in those who had been diagnosed HIV positive. The desire of being left in peace prevailed in those who had avoided the disease, as if for them the idea of being part of the community had become synonymous with the fear they had lived in and which they no longer wanted to face.

Very soon these conflicting responses to the contamination at an individual level would be dramatically echoed in the associative dynamics of the Italian hemophiliac community.

The Rise of the Compensation Issue and the Hemophiliac Community Breakdown

Until 1987, indeed, the IHF and its network of provincial and regional associations throughout Italy were still united in the common task of representing class interests. For instance, beginning in 1985, the IHF pressed regional health authorities to obtain separate hospital care for hemophiliacs with full blown AIDS from other terminally ill patients. Some regions, like Lombardy¹⁰³, released the necessary financial support on the basis of the clinical specificity of the hemophiliac-with-AIDS care¹⁰⁴.

The news of the first compensatory claims raised by hemophiliacs in foreign countries as consequence of the contamination began to circulate among Italian hemophiliacs in 1987¹⁰⁵. The community was bewildered. Most of its members had never experienced activism. They had been constantly informed by the IHF bulletin, had paid annual dues, were possibly part of local associations. But the representational strategies with politicians and public institutions¹⁰⁶, until then, had always been a prerogative of the executive committee of IHF. Protected by the legal rules of the *Fondazione*, the IHF's leadership had never changed since the establishment of the organization.

¹⁰² Ex, 14:7, July 1987, 4.

¹⁰³ Second regional plan for the fight against AIDS, in Bulletin of the Lombardy region 1 June 1988).

¹⁰⁴ To a certain extent, this "separate hospital housing" issue may raise the idea that hemophiliacs were willing to obtain a tangible acknowledgment of their condition of "different victim" from the stigma associated to the "I-have-been-looking-for-it" categories of AIDS patients (namely, intravenous drug users and gay people). Interviewed, the IHF executive secretary denied this interpretation, pointing out that the structural inadequacy of the Institutes for infectious diseases in the Italian hospitals at the time was such to justify the hemophiliacs' claim of being treated at the Hemophiliac Centers by their "familiar" medical staff.

¹⁰⁵ Compare, for instance, Ex, 14:7, July 1987, 6, reporting the news that British hemophiliacs had been invited to sue pharmaceutical companies responsible for the distribution of tainted-AFC.

¹⁰⁶ D.KIRP, The politics of blood: social movement mobilization in the AIDS crisis, in BAYER and FELDMAN.

In this context, it became crucial to devise a common strategy to support the plea for compensation. According to the IHF leadership, any action to be pursued, be it in court or in the political arena, had to take into account the need for safeguarding the privacy of the HIV positive hemophiliac. The public stigma associated with AIDS was the primary concern for the majority of the victims of contamination¹⁰⁷. The general AIDS Act of 1990 had still to come¹⁰⁸, and the perspective of being exposed to discrimination, once the identity of the plaintiff had appeared on the record of a lawsuit, prevented many of them from acting. Accordingly, IHF was in favor of establishing a dialogue with institutions, seeking political contacts to support the hemophiliac claim in Parliament.

Angelo Magrini, President of the Piedmont Hemophiliacs Association based in Turin, was not convinced by the IHF's line. For him it was time to react and, if necessary, to protest loudly. Any means could be used to shed light on the hemophiliacs' tragedy and to rally public opinion. It was time to capture the individual rage of those who had been betrayed by blood. Along with hemophiliacs, many blood recipients lacking of any collective benchmark were facing the same drama in Italy. This common rage had to be conveyed in the struggle for compensation.

This clash of strategies led in the summer of 1988 to the foundation of the *Associazione dei Politrasfusi Italiani* (Italian Multi-Transfused Association, hereinafter: API), which by choosing this name set out to represent the common interests of hemophiliacs and transfusion recipients, jointly affected by the unique life-and-death dichotomy of blood. There was a strategic intuition in the idea of setting up a common representational identity based on the drama of contamination, despite the vast differences existing between the two classes¹⁰⁹. Clearly, this would have amplified the bargaining power with politicians and institutions, by presenting a larger "social bill" when pressing for compensation. The same card might have been played with the media, which in fact were to be extensively used by the API in the course of its action¹¹⁰.

But, above all, this collective front could capture a key element in the by-standers' perception of the HIV-tainted blood contamination. For a host of self-evident considerations, blood recipients, unlike hemophiliacs, were not (and could never have been) a class. Each individual, in the course of his/her life, is confronted with the prospective of becoming a blood recipient. A woman after a cesarean childbirth, a teenager after a motorbike crash, any person undergoing a surgical operation. In the tragedy of HIV contaminated blood, blood recipients were the "every one of us". The rhetoric of the "it-could-happen-to-anybody", therefore, became available to the API's representational action. It was to be used as a central element of the collective action both for the past (that is, the quest for compensation) and the future (the call for improved blood safety).

¹⁰⁷ Interview at Umberto Randi, October 1995.

¹⁰⁸ Law 5 June 1990, n.135. Among a set of measures for the prevention and the fight against AIDS, this Act provided anti-discriminatory rules for individuals testing HIV-positive and introduced a specific prohibition for public disclosure of data concerning the seropositive status.

¹⁰⁹ Magrini's intuition was shared by the Péron-Garfanoff brothers, who founded the French *Association des Polytransfusés* in 1989, M.STEFFAN, France, in BAYER and FELDMAN.

¹¹⁰ In the course of a few years, the name and the face of Angelo Magrini, the API's leader, became well-known to the public, due to his frequent appearance in talk shows and journalistic programs of Italian television. The media was attracted by the public exposure of the personal dramas which often accompanied his TV appearances. According to the API's strategy, the emotional impact of personal stories of individuals who, challenging the AIDS stigma, were persuaded by Magrini to appear on TV was often used for the Association's cause.

The Compensation Claim in the Italian Political Arena: The Battle of the Bill Proposals

To approach Parliament has never been difficult in Italy. Among the more than nine-hundred Italian Deputies and Senators elected every legislature, even the smaller local group of pressure does not encounter too many difficulties in finding an ear ready to transform the group's particular interests in an *ad hoc* bill proposal¹¹¹. As comparative analyses report, the volume of statutes introduced each year by the Italian law-makers finds no counterparts in the context of western democracies, with the notable exceptions of the US Congress and the Swedish Riksdag¹¹². This fertility, though, is paid in terms of legislative quality of the proposed bills: the diminutive term *leggine* is commonly used in Italy to indicate the plethora of "by-laws statutes" resulting from this fragmented and narrow-aimed exercise of law-making. The great majority of these *leggine* never see the light on the legal bulletin¹¹³.

In this respect, the role of the Italian political parties is critical. "...Inundated with thousands of private member bills, but (...) paralysed when faced with major programmatic legislation..."¹¹⁴, the Italian Parliament is not easy to go through for interested groups not willing to accept the necessary mediation of political parties. Therefore, for an interest group getting the personal political commitment of a single law-maker or even of a group of parliamentarians may lead to little or no result in terms of successful legislative outcome¹¹⁵. Conversely, the chances of legislative success of a bill proposal increase considerably when this is promoted by the Executive¹¹⁶.

In this context, IHF and API, joint but separate, begun to seek political contacts in the Roman corridors of *Montecitorio* and *Palazzo Madama*. The art of lobbying provides a long list of strategic steps to gain the law-makers' attention¹¹⁷. Yet, the strategies selected by the two groups totally differed. The IHF relied on its well-rooted tradition of advocacy for the Italian hemophiliacs. To a certain extent, this "official" identity of the organization smoothed the path of IHF toward law-makers. This was not the case for the API, which needed to build up its representational role before the Parliament members.

¹¹¹ For this prerogative of the Italian democracy, G.PRIDHAM, *Parliamentarians and their constituents in Italy's party democracy*, in V.BOGDANOR, *Representatives of the people? Parliamentarians and constituents in western democracies*, Cambridge, 1985, 158; S.BARNES, *Representation in Italy: institutional traditions and electoral choice*, Chicago, 1977, 12.

¹¹² International Centre for Parliamentary Documentation, *Parliament of the world: a comparative reference compendium*, London, 1986, 909 ss. The US specificity is due to the fact that all bills are introduced by individual members of the Parliament regardless of whether or not the initiative derives from the executive.

¹¹³ Just to give an idea of the Italian legislative output, 3618 private member bills were proposed in the House of Deputies during the 9th Italian legislature (1983-1987). Of those, only 385 effectively passed (this number encompasses also bills first presented in the Senate), P.FURLONG, *Parliament in Italian politics*, in P.NORTON, *Parliament in western Europe*, London - Portland, 1990, 64.

¹¹⁴ In these terms, S.TARROW, *Italy: crisis or transition?*, in P.LANGE, S.TARROW, *Italy in transition. Conflict and consensus*, London, 1980, 178.

¹¹⁵ G.PASQUINO, *Istituzioni, partiti, lobbies*, Rome - Bari, 1988, 99.

¹¹⁶ For the dominant role of executive promoted legislation in the European democracies, E.C.PAGE, *Burocrazia, amministrazione, politica*, 1990, Bologna, 89 (originally id., *Political authority and bureaucratic power. A comparative analysis*, 1985, Brighton).

¹¹⁷ C.MILLER, *Lobbying government. Understanding and influencing the corridors of power*, London, 1987.

Not surprisingly, the first narrative of “institutional blame” presented to public opinion to support the hemophiliac claim for compensation, appeared in an article published by *La Stampa*, the Turin newspaper with national diffusion, at the beginning of 1989. It headed “AIDS, infected owing to the State’s negligence”¹¹⁸. Few months later, a leading Italian newsmagazine headed again “AIDS from the State”¹¹⁹, telling the sad story of Rocco Micò, the Italian “Ricky Ray” who died of AIDS in 1987 at the age of eleven. A few months later the same news magazine blew on the fire, reporting the news that 70% (!) of the Italian hemophiliacs had already been contaminated¹²⁰. This press mobilization prepared the ground for the breakthrough of the hemophiliacs cause into the legislative arena which, in fact, followed a few months later.

A first Bill proposal was presented in the Senate at the end of 1989¹²¹. The proponents were acting on behalf of the IHF. Accordingly, the draft envisaged a no-fault compensation scheme to recover *only* the damages suffered by hemophiliacs or other consumers of pharmaceutical products derived from blood. The political syllogism selected to support the initiative was based on the guilty delay of the Italian State¹²² in enacting the National Blood and Plasma Plan. If tempestively implemented, as the IHF had demanded since the ‘70s, the Plan would have made national self-sufficiency possible, avoiding import dependency and, therefore, HIV contamination of AFC recipients. Instead, the preamble continued, hemophiliacs had received AFC “...almost totally obtained from plasma of American mercenary donors”. This conclusion was reinforced by emphasizing that English factor IX deficient patients escaped contamination because in the UK these AFC were obtained wholly from national plasma. Further comparative references were made, albeit generically, to European countries which already compensated hemophiliacs, and to France, where, it was stated, the Health Ministry had already approved a compensatory bill that was about to be enacted.

The introduction of the no-fault plan was also buoyed by specific legal considerations. The injured minority was presented as a class of forced consumers of State-guaranteed life-saving medicines, included in the National Drug List. In order to recover damages from pharmaceutical companies, it was pointed out, HIV-contaminated hemophiliacs could not rely on the newly enacted Product Liability Act of 1988, since this expressly barred action for products marketed before that date.

Accordingly, the establishment of a State-financed fund administered by an *ad hoc* agency was seen as the only equitable solution. This latter was to act as a first-pay insurance for the injured and then, possibly, could set a recourse claim against pharmaceutical companies. In this way, HIV-contaminated hemophiliacs were to forego the hardships of a piecemeal litigation against pharmaceutical companies. The plaintiffs’

¹¹⁸ AIDS, malati per colpa dello stato, in *La Stampa*, 15 February 1989.

¹¹⁹ G.MILANO, AIDS di Stato, in *Panorama* 2 April 1989.

¹²⁰ G.MILANO, Solo sangue DOC [Only controlled denomination origin blood], *ibid.*, 18 June 1989.

¹²¹ Bill proposal n. 2019, 19 December 1989, Senators Corleone and others, in *RIML.*, 1990, 991.

¹²² A non-Italian reader may find the reference to the term “State” vague. This expression is instead extremely significant. Its Italian use in this context impinges in the Italians’ social (and historically grounded) attitude of relating to a superior, indefinite entity, *lo Stato*, which, according to the circumstances, may stand for the Parliament, the Government, both of them or even the entire community of tax-payers. As LaPalombara would put it: “(T)he continental tradition centers on the collectivity, as embodied in the state. The state grants or denies privileges on behalf of that collectivity” (*id.*, quoted above, at 261). This does not prevent that, when sued by private citizens, the *Stato* is always personified by the government minister competent for the case.

inconveniences in filing a tort lawsuit based on negligence against AFC producers were reviewed: to establish the evidence of the administration of one (rather than another) give brand of AFC and of the precise timing administration; the high cost of legal fees¹²³; the fear of undergoing a public trial; the possible diversity of the judicial outcome.

Concretely, damages were to be awarded following the ordinary quantification applied after courts in personal injury claims. In case of death, the award could be made to the spouse, to the parents or to the son of the injured. A time-bar of ninety days from the filing of the administrative claim to the Fund was prescribed for the examination of the record, with an additional sixty-days time-bar for the payment of the awards. With the due differences, the legal architecture of the IHF Bill proposal was quite similar to that which was to be endorsed by the French compensation plan in 1991.

Totally different in its philosophy, a new bill proposal followed in February 1990, this time presented in the House of Deputies on the API's behalf¹²⁴. The preamble referred to the State in terms of 'unmindful' or 'insensitive' and contained a vibrant indictment of the Italian blood system regulations, which the State had left unmodified for twenty years without deeming it necessary to adopt a national blood and plasma plan. The serious consequences were illustrated: Italy was still compelled to import more than 75% of its plasma needs, and the imported plasma was obtained from paid South American, African and Haitian donors. Also denounced was the Italian Health Authority delayed adoption of heat treatment and mandatory screening of every donation of plasma to be used for AFC, pointing out that these measures had been effectively implemented only starting from the 1986 *Circolare*.

Upon this premise, the Bill's policy was to take into account the protection of a vast array of individuals exposed to HIV contamination via bodily fluids: hemophiliacs, blood recipients, hemodialyzed, organ transplant recipients. The aim was twofold: prevention for the future and compensation for the past. A National Commission for the assistance and protection of multi-transfused subjects was to be set up, its tasks being to set up measures to prevent the possible recurrence of new viral contamination, as well as to grant compensation for those who had been infected by HIV. Damages were to be awarded on a lump-sum basis: approximately \$200,000, at the Commission's fact finding on the administrative claim; a further \$200,000, at the time of the claimant's death, to be awarded to the spouse, the parents or the son of the injured.

The API's bill was presented again in the House of Deputies on July 1990, with some significant amendments¹²⁵. The reference to organ transplant recipients and emodialyzed patients had disappeared, but, for the first time, the compensation proposed was extended also to HCV victims. The preamble did not mention considerations on State-budget constraints or on scientific evaluations of the incidence of the virus among multi-transfused to support this extension. Probably, the then fresh discovery of the causative virus of the NANB hepatitis was considered by the proponents just as a striking opportunity to add the issue to the legislative agenda¹²⁶.

¹²³ In the Italian legal system the contingency fee is banned and the "loser pays all" rule apply, see *infra*.

¹²⁴ Bill proposal n.4590, 16 February 1990, Deputies Massano and others, in RIML, 1991, 659.

¹²⁵ Bill proposal n.4928, 3 July 1990, Deputies Caria and others, in RIML, 1991, 670.

¹²⁶ J.A.CUTHBERT, Hepatitis C, *Am J Med Sci* 299 (5): 346-355 (1990); T.G.WREGHITT, Antibody avidity test for recent infection with hepatitis C virus, *Lancet* 335, 789 (1990).

As mentioned before, at the time of presentation, the above proposals might have been judged naive or, rather, utopian by an impartial analyst of the dynamics of the Italian Parliament. Clearly, these proposals (and particularly the API' ones) entailed an incalculable (yet, surely heavy) financial burden for the Treasury. Despite a flourishing welfare tradition¹²⁷, the issue of compensating victims of iatrogenic diseases was completely new to the Italian political agenda. And it was also ideologically neutral. Law-makers who accepted to support the different claims of the IHF and the API did not have a uniform political color. The signers of the Bills came from the left, the extreme right and the parties of the government coalition. Behind an issue with no political identity, there were citizens belonging to a well defined minority lobbying for a legislation which would benefit them personally. And Italians, Italian legislators at least, traditionally were likely to see in what in other democracies would have naturally been considered a "self-interested democratic participation" a search for personal advantages, and, as such, politically unacceptable¹²⁸.

Stumbling into Favorable Legal Arguments: On How the Legal Process Can Ease a Political Struggle

On June 22, 1990, the Italian Constitutional Court issued a landmark decision. In the *Oprandi* case the Court declared unconstitutional a 1966 Act imposing mandatory antipolio vaccination, because it did not provide just compensation for those injured as an accidental consequence of the inoculation¹²⁹. In case risks inherent to the vaccination and not due to medical malpractice were to befall on the vaccine recipients¹³⁰, the Court ruled that these latter should not bear the consequences of an act imposed in order to enhance public health. *Oprandi* held the State accountable for compensating such (no-fault) damages, arguing from Art. 32 of the Italian Constitution, which protects the health of each individual as a fundamental right. The opinion, though, framed the ruling in order to make it clear that this did not conceptually impinge in tort law. In this case, the State could not be deemed legally accountable for the breach of a duty of care. The deterrent function inherent to tort law was misplaced in a case in which the injury was the unavoidable consequence of a mandatory therapeutic treatment. It was a matter of "pure" compensation or, more precisely, of indemnification.

Therefore, albeit not explicitly, the Court followed the logic applied in property rights takings, as if the health of the individual injured by the vaccination had undergone to a taking for public utility¹³¹. First, damages were to be quantified as if they had been

¹²⁷ LAPALOMBARA, quoted above, 54.

¹²⁸ R.D.PUTNAM, *The belief of politicians. Ideology, conflict and democracy in Britain and Italy*, 1973, New Haven-London, 228.

¹²⁹ Corte Costituzionale 22 June 1990, n.307, *Foro.it*, 1990, I, 2694.

¹³⁰ Ms. *Oprandi*, the plaintiff in the case decided by the Court, was the mother of a child inoculated with anti-polio vaccine. It was established in court that she had become paralyzed as a result of contact with the bodily fluid of the children, while this latter was at risk of transmitting the polio virus with which he had been inoculated.

¹³¹ This idea has a close relationship with the thought of Munzer: "I deal here only with the moral and political problem of takings. In addition, I place to one side a pair of issues that is at least adjacent to the problem of takings. One concerns government action that affects person' freedom over their bodies. Example include laws requiring military service or restricting abortion. Some may find bizarre that anyone would even imagine that such laws take private property. But if persons have property rights in their bodies, then government action adversely effecting these rights might be a taking. If there were a taking, then the government might have to pay compensation or even abandon its action", S.R.MUNZER, *Compensation and*

awarded in an ordinary personal injury claim, taking into account medical expenses, lost income and pain and suffering. Then, the award had to be equitably reduced, just in order to consider the lack of negligence on behalf of the State.

For the first time, the legal process urged the Italian State to act as social insurer for a particular class of disabled people¹³². Clearly, the Constitutional Court's ruling confronted the Parliament with the need to legislate on the issue, since the Court had made manifest that compensation for vaccination-related injuries could not be regarded as a matter of tort liability.

Yet, the victims had received a vested cause of action which entitled them to obtain compensation from the State. A delay in adopting a compensation plan for those injured by vaccinations threatened financial disaster for the Treasury. The ruling of the Court, albeit not formally binding on Parliament, could open the way to lawsuits against the State to be filed by the many people in the same condition as Ms. Oprandi. Damage awards as large as the one she obtained in the remand judgment from the constitutional court ruling would have quashed the State budget¹³³.

With a remarkable sense of timing, three weeks after the *Oprandi* decision, a group of Deputies presented a Bill aimed to set up a general compensation plan for all the victims of diagnostic or therapeutic treatments, which was *also* to consider the compensation demanded by hemophiliacs and transfused patients¹³⁴. This proposal was far more ambitious than the ones already examined: it had been drafted by expert jurists and sought to systematize the *Oprandi* ruling into the legal system.

The preamble was itself a documented essay on the legal issues raised by the (increasingly delicate) relationship between health and medicine. It presented data on the spread of the contamination in Italy and quoted an estimate by the API that predicted more than 1,000 cases of HIV-tainted blood victims in the years to come. Data presented at the San Francisco International AIDS Conference in June 1990 on the global dimension of the hemophiliac contamination were described, as well as comparative data on successful compensation claims lodged by hemophiliacs in several industrialized nations, quoting the 1987 Danish Act, the 1989 French public and private solidarity Fund, the 1976 German drug-producer liability Act, the English forms of welfare. The preamble pointed out that the risk of HIV transmission was also present in transplants and artificial insemination, and that hepatitis C infection was widespread among blood recipients. The still real window-period risk for blood transfusion recipient was mentioned to underline that there was the need for legislating for the future. Quoting the *Oprandi* ruling, it was remembered that the rules of tort liability of the Italian Civil Code were often unable to offer judicial redress to those injured by these new health threats.

The core of the proposal was the concept of "biological wealth" of the individual. The legal foundations of this concept, the preamble explained, were to be found in the case-law implementation -- after a 1986 landmark by the Constitutional Court -- of the

government taking of private property, in J.W.CHAPMAN, *Compensatory justice: NOMOS XXXIII*, 1991, New York, 195, at 197-198.

¹³² G.PONZANELLI, *Lesione da vaccino antipolio: che lo Stato paghi l'indennizzo!*, in *Foro.it*, 1990, I, 2697.

¹³³ The Tribunal of Milan quantified in \$700,000 the total damage that would have been awarded to the plaintiff in a personal injury case. It then equitably reduced the amount actually awarded to \$420,000. See Tribunal of Milan 20 December 1990, in *Foro.it*, 1991, I, 1239.

¹³⁴ Bill proposal n.4964, 12 July 1990, Deputies Bernasconi, Rodotà, Violante and others, in *RIML*, 1991, 1017.

legal notion of “biological damage”. Under this notion, which was first developed by legal scholars in the ‘70s, the Italian jurisprudence had increased the award of damages in personal injury cases, assigning a *per se* value to the individual’s health, apart from the loss of earning capacities. With no intention to be precise from a comparative law standpoint, this concept granted to Italian courts the possibility to award damages that, in common law terms, would be classified as loss of enjoyment of life and loss of expectation of life.

Arguing from a legal scholar perspective, the proposal envisaged: the establishment of a National Scientific Commission with the task to drawing up uniform criteria for the safety of therapeutic and diagnostic treatments and the quality of drugs, blood and other human materials, as well as for the safety of diagnostic and therapeutic equipment; a strong administrative decentralization of the blood system; an express provision that qualified blood as a product in order to make available the 1988 Product Liability Act to HIV-tainted-blood-related claims; the inclusion of the so-called “development risks” in the field of application of this Act; the establishment of a National Fund under the Health Ministry’s supervision, which, before the pharmaceutical companies liability could be legally ascertained, was to act as a first-pay insurance for the injured party on the condition that this latter had been treated at a public health facility or had been administered a drug included in the National Drug List.

As early as 1990, the number of legislative proposals aimed, in various ways, to support the claim for compensation of hemophiliacs in Italy was probably higher than in any other industrialized nation. This is striking if one considers that, apart from a few press articles, the issue had caused very little mobilization in the general public. Nothing similar to the French *affaire du sang contaminé* had taken place in Italy. No backward analysis had been conducted on the causes and the circumstances of the contamination. Even the number of potential claimants, in case a compensation plan was to be enacted also for transfusion-related cases of contamination, was unknown.

Still, the issue of compensation had been statutorily packaged, namely, it had been inserted into the agenda of the Italian legislative process. And, by undergoing this process of “statutorization”, the political claim had been enlarged. From “compensating *only* hemophiliacs”, to “compensating *also* blood recipients”, “compensate *also* HCV victims”, up to “compensating *all* the victims of therapeutic treatments”. This escalation had left unsolved the many issues which should be carefully evaluated before enacting a compensation plan for victims of iatrogenic diseases¹³⁵. And, above all, the most trivial one, namely, how the plan was to be financed¹³⁶.

The Claim for Compensation in the “Maelstrom” of the Italian Law-Making Process

The story of the enactment of the Italian compensation plan reveals the secret dynamics of the Italian legislative process. This, metaphorically, may be aptly defined a “maelstrom”. The Government, in fact, ignored all the above examined bill proposals, and

¹³⁵ J.STAPLETON, *Disease and the compensation debate*, 1986, Oxford - New York, at 183: “(U)ntil there is a re-evaluation of such fundamental issues as why, if at all, the disabled should be treated preferentially over victims of other misfortunes, there will not be much gained from formulating detailed designs for schemes and benefits. The daunting lesson to be learned from a disease focus is that the “compensation” debate is fundamentally and disturbingly more complex than we have generally assumed”.

¹³⁶ A.R.KLEIN, *A legislative alternative to “no cause” liability in blood product litigation*, in 12 *Yale J. on Reg.* 107, 115 (1995).

it also ignored the protests of both the IHF and the API until June 1991¹³⁷. That June, the International AIDS Conference was to be held in Florence. The world media were to cover the event, along with thousands of AIDS activists from all over the world.

It was probably not incidental that on June 16, 1991, four days before the opening of the Conference, the Health Minister Francesco De Lorenzo personally wrote a letter to the API President¹³⁸. He gladly announced that the drafting process of the Bill which was to enact the compensation plan was at a satisfactory stage. The Minister assured his personal commitment. The Act had to be promulgated. A preliminary draft was attached to the letter to prove his good will. It envisaged a public-private solidarity fund with a financial contribution by pharmaceutical companies amounting to the 0.025 percent of their total revenue from the sale of drugs included in the National Drug List¹³⁹. This contribution by the pharmaceutical companies was met positively by the leaders of the hemophiliac movement¹⁴⁰. De Lorenzo, resolute, publicly confirmed his intention to maintain this policy¹⁴¹.

Easy propaganda in view of the world's media coverage of the Florence meetings? Fear of the (otherwise possible) noisy protests by hemophiliacs during the meeting¹⁴²? Maybe both: the fact is that the draft presented in June 1991 by the Health Minister mysteriously changed when the Act finally came into force in February 1992. We shall never know if pharmaceutical companies would have wished to contribute to the compensation plan that had been promised by De Lorenzo, who, incidentally, will be politically swiped away by the "clean hands" scandal in 1993¹⁴³.

¹³⁷ These protests were reported by the press: see *La denuncia e la speranza degli emofilici* [The hemophiliacs' denunciation and hope], in *CDS*, 26 March 1990; *Milano, Colpiti nel sangue* [Struck in the blood], in *Panorama*, 19 May 1991: public protests and denunciations of API and IHF increased after the eruption of the French blood scandal in 1991.

¹³⁸ The letter was published in the API bulletin: *Emonews*, September 1991, 3.

¹³⁹ "... (A) loss-based compensation system could not achieve precise and corrective justice and deterrence unless premiums (or taxes) financing the system were calibrated to responsibility for losses covered by the system and paid by potential injurers...", K.S.ABRAHAM, L.LIEBMAN, *Private insurance, social insurance, and tort reform: toward a new vision of compensation for illness and injury*, 93 *Colum.L.R.*, 75, at 91 (1993).

¹⁴⁰ U.RANDI, *Trattamenti obbligatori, trattamenti obbligati e indennizzi per i danni*, in *Diritti dell'uomo* 3, 1991, 53.

¹⁴¹ *Id.*, Interview with the Health Minister Francesco De Lorenzo, *ibid.*, 22.

¹⁴² The Florence International Conference events illustrate the weakness of the level of political identity and organized action displayed by the Italian gay groups vis-à-vis AIDS issues. This can retrospectively explain why in the Italian HIV-tainted blood saga there is no trace of interaction or contrast between the gay and hemophiliac communities, as in other national experiences. When the gay communities, present in Florence, decided to march through the center of the city, the Italian group – supposed to lead the march – hesitated. The French, German and American groups started marching, using the "ACT UP!" international movement's strongly politicized slogans: "Stop the profiteers", "Act up, fight AIDS, fight back", "Stop AIDS now", "Doctor fascist, take out the new drugs from your trays", etc. The Italian gays who participated in the march were unimpressed by the quarrelsome protests of the foreign groups. When, during the conference, the *Deutsche AIDS Hilfe* showed some video clips with explicit safe sex scenes, comments from the Italian gay community were inspired to criticism: "we don't have to exaggerate, we don't have to endanger our relationship with institutions". The isolated initiatives of some "ACT UP!" militants from New York, Paris and the Netherlands during the conference, were seen with a mixture of distrust and aloof superiority by the Italian gay leaders. See, also for further information on the Italian gay community's reaction to the AIDS epidemic, M.CONSOLE, *La funzione dei gruppi sociali nella percezione della malattia*, in *Il libro italiano dell'AIDS*, quoted above, 31.

¹⁴³ The former minister is currently undergoing a criminal trial, having been accused of extortion and corruption.

What the Neapolitan Minister had solemnly promised to the hemophiliac community, became, in its final version, nothing more than a badly amended variant of an old preliminary draft which had been prepared in 1986 by the Health Ministry, in coordination with other Ministries (Internal Affairs, Justice, Treasury, and Defense) to compensate the vaccination-related injuries¹⁴⁴. It had, until then, been locked up in the ministerial archives, provoking intervention by the Constitutional Court.

As previously noted, the *Oprandi* ruling in 1990 had forced the Government to consider the issue of vaccination-related injuries, under pain of financial disaster for the Treasury. In the meantime, the hemophiliacs claim for compensation had been placed in the political agenda. This coexistence of legislative proposals to be urgently enacted resulted in a jumbled statutory text. Despite the fact that the legal, medical-statistic and economic foundation of a no-fault plan greatly differ according to the kind of personal injury that the plan is addressed to compensate¹⁴⁵, the legal scheme of the Act that, eventually, endorsed the blood victims claim, was the one drafted in 1986 for vaccine-related injuries, only slightly amended to consider new classes of claimants.

The attempt to understand the reasons behind this cross-eyed legislative outcome leads to consider the hidden core of the Italian legislative process¹⁴⁶. Before being enacted, statutory law in Italy is always subject to a lengthy process of approvals by the two legislative assemblies. The iterant game of amendments and correlative re-passing of the texts is time-consuming. Therefore, if a draft has been approved by, say, the House of Deputies, Senators face the amendment's dilemma: to approve the statute as it is or to return it to their colleagues in *Montecitorio*. This may cost months of delay.

In the hemophiliac compensation plan's case, Parliamentary Reports state that Senators have encountered precisely this dilemma. In January 1992, the Senate Assembly, in the presence of the Health Minister¹⁴⁷, voted so that the compensation plan designed for vaccine-related injuries absorbed the others bill proposals expressly drafted in order to compensate blood victims¹⁴⁸. The former, in fact, had been already passed in the House of Deputies, and Senators were aware that there was no time left. That February, the mounting crisis of the government coalition was to send home the members of the Parliament, with the President of the Republic holding new elections. And this would have paralyzed the hemophiliacs hope for months.

Even so, it was not easy for the plan to be definitively approved. The last parliamentary vote for the Act was held the day before the end of the tenth legislature of the Italian Republic. In Italy this is supposed to be a rush time for law-makers, when traditionally the legislative outcome increases proportionally to their acquired consciousness of having to deal with re-election campaigns.

¹⁴⁴ Draft Bill n. 3730 presented to the House of Deputies and to the Senate on 7 May 1986, in RIML, 1986, 1243.

¹⁴⁵ For a general overview, S.A.M.MCLEAN, Compensation for damage. An international perspective, 1993, Dartmouth.

¹⁴⁶ Compare D.FARBER, P.P.FRICKY, Law and the public choice. A critical introduction, 1991, Chicago - London, at 153: "...legislative outcomes may be the product of the legislature's structure and procedures, rather than being any simple reflection of voter preferences."

¹⁴⁷ On January 21, 1992, the API's leader wrote an open letter to De Lorenzo that was also sent to the Italian newspapers: it began "(W)e are fed up with promises, with bureaucratic delays, with the Health Minister".

¹⁴⁸ Parliamentary reports, Senato della Repubblica, discussion of January 30, 1992.

On March 3, 1992, the Act 210/92 was published in the legal bulletin¹⁴⁹.

The Enactment of the Compensation Plan and its Legislative Stabilization

The classes of injured parties entitled to claim compensation under this Act, reveal to have nothing to share but the fact of having been listed in a section of a statute. They are: a) whoever has been injured by mandatory vaccinations and suffer from permanent disabilities, as well as who suffers from permanent disabilities resulting from contact with these latter; b) recipients of HIV-tainted blood or blood products; c) post-transfusional hepatitis sufferers; d) health care workers contaminated by HIV as a result of workplace exposure; e) health care workers suffering from permanent injuries as a consequence of non-mandatory vaccinations made in order to prevent work-place hazards; f) whoever suffers from permanent disabilities as a consequence of non-mandatory vaccinations made for reasons of work or for traveling abroad.

The financial provisions for the claimants totally burdened the National Treasury, but were much less than what hemophiliacs had demanded. A non-joint monthly life pension amounting to about \$700 and calculated according to the legal criteria applied for the disabled ex-servicemen pensions, was to be paid to the claimants starting from the month following the filing of the claim. In case the claimants should die a lump sum of approximately \$35,000 was to be awarded to the relatives (but solely if they financially depended on the deceased person) in the following order: spouse, minor son, major disabled son, parents, minor brothers and sisters, major disabled brothers and sisters.

A time-bar of ten years from the actual notice of the HIV contamination was established for filing the claim (reduced to three years in case of infection from hepatitis). For those already contaminated by the date of enactment of the Act, a shorter three-years time-bar was set. Concerning the determination of the claim, the onus was on the claimant to furnish medical documentation in order to establish when, how, and from which transfusion event or AFC administration the HIV contamination stemmed. Paradoxically for hemophiliacs, who have always been Army-exempted, the military medical commissions were appointed for evaluating the causal link between the event and the contamination. Finally, the compensation scheme did mention any estoppel for claimants willing to file a tort lawsuit against the potential “responsible” for their contamination.

Reviewing all the legal problems raised by the formulation of the Act would be misplaced in this context; suffice here to say that its legal provisions were themselves evidence of the hasty climate in which they had been approved by the Parliament. From a political standpoint, the Act betrayed the blood victims’ expectations: the financial relief envisaged was a meager pay even for covering the everyday needs of those living with HIV. Very soon, both the API and the IHF publicly raised their discontent: the lump-sum award set to compensate the tragic death of the victim of blood contamination was renamed by the hemophiliac representatives a “mite from the State”, to signify its inadequacy to compensate for the death of a beloved.

Finally, after three years of protests by the API and the IHF, the Italian Government emended the Act, issuing in August 1995 a Decree-law which raised the lump-sum to approximately \$100.000¹⁵⁰. The Decree also introduced other positive amendments for the beneficiaries of the Act. The lump-sum was to be due to the relatives

¹⁴⁹ In GU 6 March 1992, n.55.

¹⁵⁰ Decree-law 28 August 1995, n.362 (in GU 30 August 1995, n.202).

of the deceased party also if they did not depend financially on the original claimant. The life pension and the lump-sum in case of death were to be autonomously claimed also by the spouse infected through sexual intercourse with the contaminated partner, and also by the child contaminated through the mother during pregnancy. Claimants who suffered from more than one disease (as in the case of coexisting contamination by HIV and HCV) were to receive supplementary awards. The administrative task of determining the claim was given to civil health facilities, instead of military medical commissions.

Unfortunately for claimants, these amendments were enacted by means of a Decree-law¹⁵¹. Starting from August 1995, these new provisions were kept in force by the Government by re-enacting the Decree every two months, until December 1996, when finally these new provisions were converted into law by Parliament¹⁵².

The Implementation of the Plan: An Example to Forget

One of the pivotal reasons that militate for the enactment of a no-fault compensation plan is to ensure quick relief to a group of victims of misfortunes, enabling them to by-pass the burden of an uncertain action in court¹⁵³, and allocating the litigation-related transaction costs to compensate the injureds for the losses¹⁵⁴. However, in the drama of the victims of HIV-tainted blood contamination, quick relief *is* the issue at stake. Accordingly, it had been hoped that the initial ‘meager’ compensation of the 1992 Act would at least be counter-balanced by an efficient administrative handling of the claims filed, in order to guarantee a prompt and effective response to demands for financial support.

At the end of 1992, the claims received by the Health Ministry already amounted to 2,045, of which only 886 were examined for *prima-facie* determination. No claimants had been summoned for medical examination by the commissions in charge of evaluating the causal validity of the claim. These first data brought to light the overwhelming disproportion between claims based on blood-related HIV contamination (844) and those based on vaccine-related accidents (only 44).

While setting a time-bar for claimants, the Act did not imposed a time-bar upon the Health Ministry for settling the claims quickly. In this respect, claimants are legally defenseless, given the unavailability of an administrative law-based cause of action for speeding up the ministerial passage of the records. The no-fault plan management followed the logic of the Italian bureaucracy: Only in November 1993 did the Health Ministry create an *ad hoc* bureau, which, in the maze of ministerial departments and sub-departments, had exclusive responsibility for administration of claims based on the Act. By then, the number of claims had risen to 3,412, and no claimants had yet received a penny from the State. In May 1995, 2,511 claims had been dealt with, and many heirs had received financial relief (604 claimant had died by that time). At the same time, the number of claims received by the *ad hoc* bureau had risen to 20,140. The last figure

¹⁵¹ On the distorted use of this “pragmatic answer to serious bottlenecks in the Italian representative system”, see LAPALOMBARA, quoted above, 115. Decree-laws, requiring a two-months re-enactment until the legislative text is definitively approved by Parliament, often enable the executive to amend (at every re-enactment) important provisions of the text, with puzzling effects on the certainty of the law.

¹⁵² Law 20 December 1996, n. 641 (GU 21 December 1996, n. 299).

¹⁵³ P.S. ATIYAH, P. CANE, *Accidents, compensation and the law*, 1987, London.

¹⁵⁴ K.S. ABRAHAM, L. LIEBMAN, quoted above, at 94.

available (as of April 1, 1996) indicates the incredible number of 26,978 claims, with 3,408 pensions and 514 lump-sums already awarded for an expenditure of 171,966,164,290 lire (approximately \$110 million) by the Treasury¹⁵⁵.

In April 1996, on a petition determined by the case of a plaintiff, who, injured by anti-polio vaccine in the '60s, claimed to be compensated starting from then, the Italian Constitutional Court declared the unconstitutionality of a provision in the 1992 Act, which established the starting point of the pensions to be awarded at the time when the claim was filed by the injured party. The Court maintained that such limitation contrasted with the *Oprandi* ruling and with the constitutionally protected right-to-health¹⁵⁶. Therefore, it ruled the claimant's right to obtain the payment of the pension starting from the time when the injury actually occurred. According to this retroactive payment, and taking into account the interest rates and the inflation-adjustments of the sums due, the Treasury's expenditure for the coverage of the compensation plan will rise enormously¹⁵⁷. To date, a constitutional petition has not yet been made by the HIV contaminated beneficiaries of the 1992 Act. Should this happen, it can be easily predicted that, on the basis of the equality clause of the Constitution, the same time-extension will be constitutionally granted, entitling claimants to receive the pensions from the time when the HIV contamination was first discovered.

National budget constraints, due to the forthcoming integration of the European monetary systems, press the Italian Government today to cut welfare programs. But the legal process, as seen above, pushes in the opposite direction. Five years after its enactment, the 1992 compensation scheme has become a time-bomb for the Italian Treasury. In March 1997, press reported the Government's inability to find budget resources to be allocated for the payments of the claims brought under the 1992 Act¹⁵⁸.

Meanwhile, for the many waiting claimants the only perspective for enforcing their rights is to file a claim before the European Court of Human Rights. Possibly, only the Strasbourg Judges, by condemning the Italian Government for denying justice on the basis of art. 6 of the European Convention¹⁵⁹, will write the final chapter of the never-ending saga of the Italian compensation plan.

The Italian Litigation by Victims of HIV-Tainted Blood

Analysis of the legal controversies aroused by the HIV-tainted blood contamination in Italy must consider separately the hemophiliacs and transfusion recipients litigation.

In this latter case, in fact, factual circumstances of each lawsuit may greatly vary, and entail a cause of action based on medical malpractice, either for negligent prescription

¹⁵⁵ All the data above are documented by ministerial communications provided to the present writer by the API, after an unsuccessful formal request for information made to the Health Ministry in May 1996.

¹⁵⁶ Corte Costituzionale 18 April 1996, n.118, in *Foro It.*, 1996, I, 2325.

¹⁵⁷ In the remand judgment on the case the plaintiff of the constitutional ruling was awarded the incredible sum of \$1,2 million; see Pretura Firenze 10 October 1996, *Manichi v. Ministero della Sanità*.

¹⁵⁸ *Danni da trasfusioni in attesa* [Transfusions damages are waiting], *Il Sole* 24 ore, March, 25, 1996.

¹⁵⁹ Already in 1992, in the *X v. French Government* decision of 31 March 1992, the European Court of the Human Rights condemned the French Government for the unreasonable delay of the administrative action brought by a HIV-contaminated hemophiliac under the French compensation plan. The Court also awarded the claimant approximately \$30,000 as compensation due by the Government as consequence of this delay.

of the transfusion, or for breach of the duty of care in testing blood. The legal focus, in both cases, is in the concept of negligence, the burden being on the plaintiff to establish evidence on the elements of the cause of action. The issues at stake in this kind of litigation should be examined after reporting on the hemophiliacs legal claims, which in Italy appear to have followed a litigation strategy quite different from that undertaken by other hemophiliac national communities.

In 1990, an article published in the Italian edition of the British Medical Journal outlined a comparison of the claims for compensation lodged by HIV-contaminated hemophiliacs in several nations. Reporting on the domestic situation, the author of the article asserted that no lawsuits had yet been filed in Italy, either against the Government or against pharmaceutical companies or hospitals. This was explained on the hasty presumption that Italian attorneys, consulted by hemophiliacs, were dissuading to sue¹⁶⁰.

The National Bar Association did not sue the author of such a defamatory statement for the class, but, as early as in 1989, the IHF, with the support of the Italian Lawyer Association for Human Rights Protection, had urged HIV-contaminated hemophiliacs to address a letter to the Health Minister and to pharmaceutical companies, claiming damages and reserving the right to sue, in order to interrupt the general limitation term which bars tort actions after five years had elapsed since the injured had knowledge of the harm.

At that time, it had become clear that hemophiliac contamination involved a case of mass tort litigation, in which the legal and factual elements of each claim could be deemed common to the entire class of potential plaintiffs. Lawyers close to the hemophiliacs organizations were trying to devise a common litigation strategy for the class, being painfully aware that the Italian legal system does not provide for a procedural instrument comparable to the American class action.

For any Italian lawyer, it would have been extremely difficult, if not impossible, to gather information from hundreds of potential plaintiffs spread throughout the country, and to counsel them to sue the “responsible” of their contamination before a single tribunal. Many personal dramas were going on, with a plethora of diverse, individual reactions to the tragedy, and with a unique common fear: being forced to publicly disclose the identity of their drama once in court. In the face of these problems, it could have been useful to bargain the cost of the litigation with the clients in order to convince them to start a lengthy and uncertain action in justice against a powerful defendant (be it the State or the pharmaceutical companies), as it would have been possible for an American colleague. But this was not permitted to Italian lawyers. The “loser pays all” rule usually applies in Italy, and the rules of professional conduct of the Bar prohibit the contingency fee. Moreover, lawyers are banned from recruiting clients. A letter or a telephone call with which a lawyer attempts to reach potential clients, informing them on the possibility to sue, would be considered advertising and, as such, contrary to the law of the Bar.

These considerations may help to understand why today the number of lawsuits pending before the Italian courts as consequence of the HIV contamination is, as we shall see in a moment, quite limited. To a certain extent, they may also explain the critical role played by the two Italian hemophiliac organizations in illustrating to their members the possible strategies to be pursued in court.

¹⁶⁰ A.BONO, *Emoderivati e HIV: la questione dell'indennizzo*, in B.M.J. (Italian edition.), 13, 1990, 161.

This role is emphasized by the description of the different litigation paths which have been advocated by the API and the IHF. While the former, supporting two lawsuits filed in 1990 before the Genoa Tribunal, encouraged its members to bring a legal action against pharmaceutical companies, the latter sponsored a radically different tactic of litigation. This diverse counseling led more than three-hundred hemophiliacs to sue the Italian Government in 1993 before the Tribunal of Rome. Despite the particular and urgent nature of the claims, both the Genoa and Rome actions are still pending. Considering the controversial issues at stake, this is -- unfortunately -- not surprising. In Italy, on the average, an ordinary tort lawsuit requiring expert witness testimonies may take from four to eight years to result in a decision. The traditional slowness of the Italian machinery of justice is another factor that may have played a critical role in deterring hemophiliacs from seeking justice in court on an individual basis¹⁶¹.

The Genoa Lawsuits against Pharmaceutical Companies

On January 1990, API announced that two actions had been filed before the Genoa Tribunal against two different pharmaceutical companies (the Italian Sclavo and the Austrian Immuno). The complaints were also brought against the Health and the Internal Affairs Ministries. In both cases, the plaintiffs were parents of hemophiliac children died of AIDS after contamination resulted from administration of AFC. One of the two was the Rocco's father, who in 1995 will narrate the sad story of his unfortunate son in the only book that - to date - has outlined a story of the hemophiliac contamination in Italy¹⁶².

In the Rocco lawsuit, which differs from the other one only for the name of the company sued, facts narrate the massive administration of a brand of factor VIII AFC marketed by the Italian company between 1983 and 1986, the discovery of HIV infection in 1985, and the death of the child in 1987. The complaint alleges the Sclavo liability in marketing AFC without duly warning the consumer about the viral risk entailed by the administration of the product, while the government authorities are blamed for not having duly controlled the product before issuing authorization for sale and for not having carried out timely, while the product was marketed, subsequent control and verification measures on the contamination hazard.

From the legal standpoint, since the 1988 product liability Act does not apply to products marketed before its enactment¹⁶³, the claim is cumulatively based, both on the general cause of action codified for negligence claims by art. 2043 of the Italian Civil Code¹⁶⁴, and on the special liability clause envisaged by art. 2050 of the Code. This latter depicts a severe regime of liability for defendants who cause harm in the exercise of

¹⁶¹ The "biblical" duration of the Italian civil proceedings has been already condemned in 785 claims presented by Italian plaintiffs before the European Court of Human Rights, see *Processi lenti, il record italiano* [Slow proceedings, the Italian record], Sole 24 ore, April 9, 1996.

¹⁶² G.MILANO, G.MICÒ, *Puoi correre Rocco. Sangue e AIDS: cronaca di uno scandalo italiano* [You can run Rocco. Blood and AIDS: chronicle of an Italian scandal], 1995, Rome.

¹⁶³ It must be stressed that the Italian product liability rules consider blood derivatives to be products like all others: the legal definition of product encompasses any movable chattel with the exception of products not manufactured by a professional producer and not intended for sale. Whether this is clear for industrially manufactured blood and plasma derivatives, the same is not so obvious for fresh blood to be transfused, see *infra*.

¹⁶⁴ The article prescribes: "(A)ny fraudulent, malicious or negligent act that causes an unjustified injury to another obliges the person who has committed the act to pay damages", art.2043, in M.BELTRAMO, G.E.LONGO, J.H.MERRYMAN, *The Italian Civil Code*, 1969, Oceana, 503.

dangerous activities¹⁶⁵. Clearly, it is particularly relevant for the plaintiff to obtain the application of this stricter standard of liability to the defendants conduct, since this would overturn the burden of the proof in the litigation.

According to the general rule of liability for unlawful acts, in fact, in order to prevail, plaintiffs need to establish the damages suffered, its causal connection with the administration of the AFC marketed by defendants and the violation of a duty of reasonable care by the pharmaceutical companies. The first burden for plaintiffs is to prove the causal connection. Rather than the contamination cause, at stake is the plaintiffs ability to establish when the contamination occurred¹⁶⁶. This timing will be crucial in evaluating the claim of negligence made against the defendant companies. And it is precisely on this evaluation that the “dangerous activities standard” would apply, enhancing considerably the perspective of success for plaintiffs. Should the Genoa Court hold the applicability of this standard to the cases, defendants would have to prove that they took all the possible measures to avert the risk that AFC could be contaminated by HIV.

In order to determine whether this severe standard may apply in the Genoa lawsuits and, if so, the likely consequences on the final decision, it is worth describing the legal principles established by the (above mentioned) Trilergeran litigation, whose factual circumstances appear extremely similar to those at stake in the pending lawsuits.

The Trilergeran case has offered to the Italian *Corte di Cassazione* the opportunity to clarify whether the production, the import and the marketing of drugs should be considered a dangerous activity. When, in the second half of the ‘70s, several lawsuits were brought throughout Italy both against the two Italian pharmaceutical companies which had respectively marketed and imported the Trilergeran and against the American supplier of the gamma-globulins used for the drug production, plaintiffs sustained that the defendants’ activities were dangerous. To support this conclusion they alleged a host of considerations: the regulations then in force in the blood sector envisaged the risk of the transmission of hepatitis through blood and its derivatives, thereby qualifying their production and marketing as dangerous; scientific evidence proved that, when facts occurred in 1974, HBsAG antigen screening of plasma and serum was a widespread practice; the WHO had recommended to exclude serum testing positive for HBsAG from the production process of blood derivatives; scientific opinions, although not unanimously accepted at the time, admitted that gammaglobulins might be carriers of the hepatitis B virus.

Once established in trial that a batch of drug confections was positive for the presence of HBsAG because it had been obtained from tainted gammaglobulins supplied by the American company, the cornerstone of the litigation became the establishing of the dangerousness of the defendants’ activities and, subsequently, whether defendants had taken all foreseeable precautions to prevent contamination.

¹⁶⁵ “(W)hoever causes injury to another in the performance of an activity dangerous by its nature or by reason of the instrumentalities employed, is liable for damages, unless he proves that he had taken all suitable measures to avoid the injury”, art.2050, *ibid.*, 504.

¹⁶⁶ A major problem for the plaintiff can be accomplishing this task once several years had passed from the event: this special burden, due to the long latency of the disease, is common to all the HIV-related tort claims. Evidence are to be found in medical records: note that until 1986 Italian hospitals were not mandatorily required to archive these latter. It was only starting from a Circular issued on December 19, 1986 (in RIML, 1987, 672) that the Health Ministry ordered the unlimited conservation of medical records, establishing that each health facility must keep the registers for no less than 40 years.

The final word on this critical legal issue was pronounced by the *Cassazione* in a 1987 landmark¹⁶⁷. The Court clearly stated that all activities subject to regulation for the purpose of protecting the public safety and having an intrinsic potential dangerousness are relevant for the application of the strict standard of liability prescribed by art. 2050 of the civil code.

Concerning the alleged defense that all the precautions possible at the time had been duly taken to avoid the production of the harm, the Court maintained that pharmaceutical companies should have produced instead “positive” proof of having performed the RIA test on gammaglobulins. This, despite the fact that this test was not imposed at the time, either by the FDA regulations to which the American producer was subjected, or by the Italian regulations on the import and marketing of the immunoglobulins.

Although conceding that the RIA test was considered experimental at the time, the Court stressed that this screening was nevertheless known to the scientific community as a possible means for screening hepatitis B. As such, its adoption should have been required. Moreover, the Court extended its ruling to all the different activities (production, import, marketing) of the defendant companies. Each of the defendants’ activities, in fact, was to be considered part of a single process, which had exposed the injured recipient to the hazard resulting from the use of a drug obtained by a raw blood component at risk of transmitting viral agents.

The rule resulting from the Trilerigan litigation clearly allocates the development-risks liability to the pharmaceutical companies¹⁶⁸. This ruling has been upheld several times by the *Cassazione*¹⁶⁹, and, albeit Italian courts are not bound by the *stare decisis* principle, it is to be expected that it will find application in the Genoa lawsuits¹⁷⁰.

In the Rocco’s trial, defendant Sclavo denied its liability, arguing that AFC had been imported from Cutter Biological and that only this latter was under the obligation to test the product. The American company subsequently intervened, contesting, against the Trilerigan rule, the applicability of art. 2050 of the Civil Code to the case. In its view, the shifting of the negligence standards applies only when the harm occurs as a consequence of the inherent dangerousness of the product (as in the case of a gas cylinder), not when this feature is related to the producer’s activity (as in the case of pharmaceutical industries).

This argument is not new, since the interpretation advocated by Cutter was overruled by the Italian jurisprudence precisely on the occasion of the Trilerigan litigation. Possibly, defendants will have to face the necessity to prove that, at the time when the injured party tested HIV-positive, and according to even minority opinions expressed by the medical literature of the time, the theoretical possibility of obtaining HIV-free AFC did not even exist.

¹⁶⁷ Cass. 15 July 1987, *Foro It.*, 1988, I, 144.

¹⁶⁸ Compare D.CARUSO, *Quando il rimedio è peggiore del male: emoderivati infetti e responsabilità civile*, in *Foro It.*, 1988, I, 144, 152, quoting the example of the liability rule which resulted in the American vaccine producers “crisis” of the early ‘80s as reported by P.HUBER, *Safety and second best: the hazard of public risk management in the Courts*, in 85 *Colum.L.Rev.* 277, 285 (1985).

¹⁶⁹ In one of these decision (Cass. 20 July 1993, *Foro It.*, 1994, I, 455) the Court actualized the fairness of the rule by quoting as an example precisely the AIDS contamination risk of pharmaceutical products.

¹⁷⁰ According to a recent legal analysis on the HIV-tainted blood liability, the applicability of the Trilerigan rule in the case of AFC contamination would be out of the question, compare M.BISCIONE, *HIV da trasfusione, emoderivati e responsabilità civile*, in *Danno e responsabilità*, 1996, 145,149.

In this respect, the scientific determination resulting from the opposed views advocated by the parties' expert witnesses testimonies will be crucial¹⁷¹.

Blaming the State in Court

The claims brought against the State in the two Genoa lawsuits must be examined together with the IHF sponsored case pending before the Rome Tribunal, given their similar nature. This latter is aimed at holding legally accountable the Italian State for the shortcomings displayed in setting forth the regulatory response to prevent hemophiliacs HIV-contamination. The claim also blames the State for a twenty-year delay in setting up an efficient blood and plasma collection system. The alleged liability is based on the general cause of action for negligent conduct of art. 2043 of the Italian Civil Code.

This action has taken years to be organized and prepared. Possibly, never a single lawsuit promoted by well 340 plaintiffs was filed before an Italian Court. This enterprise was made possible through the assistance of the IHF, whose secretary, a lawyer, is also a member of the hemophiliacs defense team. The plaintiffs' concern about the risk of public disclosure of their names was dealt by asking to the President of the Rome Tribunal to apply the AIDS Act of 1990. Names were omitted in the complaint and listed in a separate document kept in the registry of the court, to be disclosed only to the defendants attorneys. Although the number of plaintiffs may stand for the contrary, the pending case is not a class action. According to the Italian rules of civil procedure, the Court has the power to split the action in separate, individual actions at any time of the proceeding.

In analyzing the hemophiliacs' claims against the State from a legal point of view, it is quite difficult to draw a clear distinction between their legal value and their political significance. The complaint narrates the political history of the Italian blood system, underlying the failure of the Italian Government in timely enacting a national blood plan. This would have permitted to achieve the Italian plasma self-sufficiency before the occurrence of contamination from AFC derived from American HIV-tainted plasma, the assumption being that plasma collected in Italy would have not carried the virus. The Government is also blamed for the belated withdrawal of unheated AFC in the period between December 1984 and July 1985.

It is a technically arduous undertaking to envisage in the Italian legal system a government liability for failure to legislate¹⁷². The Italian State was recently held

¹⁷¹ "For those who favor the law's adopting a scientific approach to selecting information for fact finders to consider, it might seem appealing for the law to adopt a scientific attitude toward uncertainty about causation. Since science and law gather information for different ultimate purposes, however, it does not make sense for the two fields to respond identically to uncertainty about matters of fact. Law and science both seek correct factual information, but the two enterprises have different interests in this information. At one level, science pursues correct information simply to achieve a better understanding of the natural world. At another level, science seeks information in order to predict -- and, ultimately, to control -- what happens in the world. Regardless of which end -- understanding or control -- motivates a scientist, the appropriate response to uncertainty is to delay reaching a final conclusion until further research settle the issue. (...) Understanding the natural world or predicting its behavior reliably requires factual corrects conclusions, but conclusiveness in and of itself has no independent importance. In law, the situation is different. Law pursues correct information in order to settle the disputes promptly, decisively, and justly. Each of these goals is sometimes best served by deciding upon a final result in the face of uncertainty about seemingly pivotal matters of fact. (...) In law, in contrast to science, closure and finality have value in their own right.", H.L.FELDMAN, *Science and uncertainty in mass exposure litigation*, 74 *Tex. L.Rev.*, 1 (1995), 1 at 41-43.

responsible for “legislative omission” by the European Court of Justice for the belated enactment of a statute which should have adopted an European Union Directive, in a claim brought by a group of plaintiffs who were financially harmed by this delay¹⁷³.

But this does not seem extensible to the current “State litigation” by hemophiliacs. In that case, in fact, the finding of State liability (limited to pecuniary losses) was supported by the argument that the Italian Government, joining the European treaty, had assumed the obligation to apply the European directives in its legal system also before its citizens. Concretely, the European decision was deprived of any positive effect for the original plaintiffs when they claimed the application of the ruling before the Italian Court of *Cassazione*. The Court rejected the European principle, arguing that the Italian legal system does not envisage the State liability for omitted legislation toward private citizens, given the Government’s full sovereignty in its political decisions and legislative determinations¹⁷⁴.

Nevertheless the “three-hundred’s lawsuit” pursues a specific strategy, sustaining that, through the enactment of the 1992 Compensation Plan, the State indirectly acknowledged its responsibility for the hemophiliacs contamination. Following this perspective, the lawsuit attempts to take advantage of the causal connection between the infection occurred to hemophiliacs and their use of AFC, as ascertained in the administrative trials held under the Compensation Plan Act. In the plaintiffs’ view, this would help to accomplish the otherwise difficult task of proving the causal connection of more than three-hundred cases of contamination. It is too early to say whether this attempt will succeed, although it must be pointed out that the causation judgment by the medical commissions of the Compensation Plan Act seems to have a loser nature than the more severe inquiry required in a tort action. Conclusively, the three-hundred’s litigation, as a completely new case, has to climb a slippery slope¹⁷⁵.

¹⁷² The Italian legal system’s tradition and, more generally, the civil law tradition historically encompasses the private/public law dichotomy. Accordingly, the government liability for failing to legislate has to confront the fact that, according to public law, public bodies are under a duty to act fairly towards citizens. This duty does not give rise to a subjective right; it gives rise only to (what is technically defined as) a “legitimate expectation” or “legitimate interest”. The result is that, so far, in Italian law the preclusive effect on a tort claims for damages based on an unlawful act or an omission by the government has substantially been similar from the exception based on the “king-can-do-no-wrong” privilege and resulting in the government (or “sovereign”) immunity from private tort claims of the common law legal tradition (J.R.ROBERTSON, The effects of consent decrees on local legislative immunity, in 56 U.Chi.L.R. [1989], 1121). In the hemophiliacs litigation attempt is made of presenting the tort claim as based on a subjective right inferred from the constitutional right to health, stressing the idea that the administrative supervision of the Health Ministry in the public health sector is eventually addressed to protect a subjective right of the citizens. In this perspective, logical arguments may be borrowed by what common lawyers would define “specific detrimental reliance” (i.e. the duty to continue past warnings which have induced reliance by the plaintiff), M.K.WOODALL, Private law liability of public authorities for negligent inspection and regulation, in 37 McGill L.J. (1992), 83.

¹⁷³ European Court of Justice 19 November 1991, *Francovich v. Repubblica Italiana*, Foro It., 1992, IV, 150 on which R.CARANTA, Governmental liability after *Francovich*, in 52 [1993] Camb. L.J. 272-297. Broadly put, the Court held that Governments of Member States shall make good any damage suffered by individuals owing to the non-implementation of EEC directives or, more generally, by any act or omission imputed to a branch of the government which turns out to be inconsistent with Community law.

¹⁷⁴ See Cass. 11 October 1995, n.10617, in *Danno e responsabilità*, 1996, 78, and the comment by G.ROSCIONE, Mancata attuazione di direttive comunitarie: la cassazione nega l’illecito dello Stato, *ibid.*, 80.

¹⁷⁵ For an anticipate negative verdict, F.MERISI, Sulla configurabilità di una responsabilità della pubblica amministrazione nell’esercizio dell’attività di vigilanza. Il caso degli emofilici colpiti dall’AIDS, in *Rass. giur. sanità*, 70, 1990.

But aside from the judicial outcome of this lawsuit, and beyond the strong political message of the action, what really surprises is that in the ‘three-hundred lawsuit’ hemophiliacs have not sued, along with the Italian State, the pharmaceutical companies. Asked to give an explanation for what appears to be an odd benevolence toward the AFC producers, especially on the basis of the pro-plaintiff legal framework existing in the Genoa lawsuits, the IHF secretary replied that the Rome lawsuit intended to force the State to call on a guarantor the pharmaceutical industries in order to be relieved from the hemophiliacs’ legal claim.

But this has not happened to date and it does not seem likely to happen in the future, since the Government lawyers sustain the complete inadmissibility of the action, for the reasons already set out.

Physician and Hospital Liability for Transfusion-related Cases of HIV Contamination

Despite the epidemiological numbers seen above, the Italian Digests do not report yet decisions on lawsuits brought by HIV-contaminated transfusion recipients. It is, nonetheless, likely that this is a temporary feature, since it is almost certain that pending litigation would be detected by scrutinizing every single civil docket of the Italian Tribunals.

In a recent unpublished case involving HCV contamination¹⁷⁶, two doctors who had administered HCV-tainted blood to the plaintiff, as well as the hospital where the transfusion had occurred, were jointly held liable for the occurrence of contamination. The claim was based on the physicians’ breach of a duty of care in deciding that the patient should undergo transfusion, since the scientific experts’ testimonies established that his pathology did not require blood transfusion as a mandatory life-saving therapeutic treatment.

The finding of negligence was supported by the ruling that doctors should have known the risk of contamination through blood transfusion, especially with regard to the HCV virus, which in 1988 (when events occurred) was well known in medical literature as an unavoidable hazard for transfused patients. The hospital’s joint liability followed on the basis of the vicarious liability arising from the employment relationship between the tortfeasor physicians and the hospital.

In the absence of case-law on the subject, discussion of the blood transfusion-related litigation entails a hypothetical analysis, which is based on the application of the concept of negligence and of the related doctrine of informed consent by the patient. The hardship in these cases, once again, is establishing the causal connection. This goal can be pursued only through a look-back analysis to find the donor’s identity. Given the lack of institutional programs, plaintiffs may find it difficult to trace the transfusion chain back to the original donor.

The standard inquiry would begin with the transfused blood unit data logged on the recipient’s medical record in order to give a name to the donor. The donor (who may be still asymptomatic) could then be requested to take a test for HIV. This gives rise to an intricate legal issue, since donors can refuse discovery on the basis of the constitutional

¹⁷⁶ Tribunal Milan 22 May 1995, Pasquariello v. Pellanda et al..

provision that shields individuals from medical treatment not imposed by an express statutory provision.

Possibly, an Italian attorney would suggest to file a criminal charge for personal injury against the responsible of the transfusion (i.e. the head of the transfusion center), in order to take advantage of the investigative powers assigned to criminal prosecutors. The criminal findings may then support the tort action. In the lack of a successful discovery, plaintiffs may confront the defendant's attempt to shed light on the personal "bad habits" of the injured plaintiff. Judges are likely to face a dilemma in which their final opinion must rely on presumptions.

On successful completion of the causal judgment, the litigation path for the plaintiff appears less problematic. Given the detailed set of technical regulations surrounding transfusion practice, any omission or error by the transfusion physician or the auxiliary personnel of the center with respect to standard practice is likely to grant a finding of negligence. Moreover, the doctrine of informed consent requires the treating doctor, who decides on the therapeutic necessity of transfusion, to inform the patient of the risks involved, pointing out (should the treatment not have been urged by imminent danger to the life of the patient) the availability of autologous transfusion¹⁷⁷. This, for instance, is the case for transfusions in cosmetic surgery.

The extension of the dangerous activity standard to medical treatment and, more generally, to transfusional practice should be excluded. The Italian jurisprudence, as well as legal scholars, maintains that the standard applies only to industrial activities, not to the personal, professional performance of physicians, which is to be subjected to the general regime of liability for negligence¹⁷⁸. Also the strict liability standard set out by the 1988 Act, should be unavailable for claims brought by HIV-infected blood recipients. Apparently, in fact, in the Italian legal system blood is considered a non-marketable good. This, apparently, would prevent courts from considering blood a product and¹⁷⁹, consequently, to apply the Act.

Economic insight, however, may well suggest the contrary¹⁸⁰. The principle of full gratuitousness of blood is endorsed by the law solely for the political choice of impeding the circulation of this good in the market. Blood, however, is not free. The costs of collection and safety of blood are considered also by the Italian law, which in fact establishes a token price for the transfer of blood bags among transfusion centers. Moreover, these costs are sustained by recipients when paying hospital fees, in case transfusion takes place in private health facilities, or through general taxation or prescription charges when transfusion is performed in public hospitals.

The Blood System Reform of 1990

¹⁷⁷ L.P.COMOGLIO, *Consenso informato e profili di responsabilità nelle donazioni di sangue*, *Foro It.*, 1992, V, 363, 373.

¹⁷⁸ According to BISCIONE (quoted above, 278) the transfusion center activity should instead be considered dangerous, according to the known and statistically foreseeable risk of transmission of viral diseases that it implies.

¹⁷⁹ In the absence of express statutory provisions, like those of the "Blood shield statutes" enacted in many States of the USA (Bayer, USA, in Bayer and Feldman), the question whether blood can be considered a product will have to be interpreted by courts.

¹⁸⁰ BISCIONE, quoted above, 279-80.

The occurrence of HIV-tainted blood contamination forced the Italian Parliament to come to terms with the need of a radical reform of the national blood system, after more than a decade of vain legislative debates¹⁸¹.

The system's inability at ensuring national supply of blood and plasma had exposed Italy to the international tragedy. This had thought to Italian policy-makers that, with regard to blood, the quality *vs.* quantity dichotomy was deceptive. The two issues should have been addressed jointly. Blood and plasma safety, notwithstanding all possible efforts to enhance and ameliorate viral screening and virucidal treatments of blood and its components, was to be pursued by achieving national self-sufficiency. By the end of the '80s, self-sufficiency in blood and plasma, after all, had become a European slogan. The Council of Europe first¹⁸² and the European Economic Community¹⁸³ (EEC, now: European Union, UE) then, urged Italy to reshape its blood system according to two general guidelines: achievement of self sufficiency and voluntary and non-remunerated blood donations.

In May 1990 the Italian blood system received its awaited general reform. A new Act repealed the twenty-three-year-old regulations¹⁸⁴, implementing the regionalization of the sector only formally declared by the 1978 Health Reform Act. Accordingly, transfusion activity is now conceived as an integral part of the National Health System. All transfusion facilities and the (few) blood derivatives production centers still directly run in 1990 by the non-profit sector (mainly AVIS in Lombardy and the Red Cross in the Rome area) are under the public aegis of the National Health System. Blood collection is based solely on periodic voluntary blood donations, and the general principle that blood donation and distribution should be completely gratuitous is affirmed¹⁸⁵.

Blood and its components can not be considered a source of profit and are declared tax-exempt. The blood collection cost, as well the fractionation, preservation and distribution ones, are charged to the Health National Fund budget, with a 'political' price (for blood units transfers between transfusion centers) being issued yearly by ministerial decree.

In order to monitor the quantity and quality of the blood produced and administered by each region, regional blood registers have been set up. The blood donor associations are institutionally involved in the administration of blood collection and are entitled to negotiate agreements with the regional transfusion authorities. Regionalization also means today the responsibility of regional authorities at issuing blood regional plans. These are conceived to be an integral part of the national blood plan. A Commission for the National Transfusion Activities (CNTA) has been created in Rome, as a consultative organ to the Health Ministry for drawing up-to-dated criteria for implementation of the national policy toward blood safety and self-sufficiency. In this board, two representatives

¹⁸¹ ZANA, quoted above, 840, reporting and discussing several proposals of reform under examination by the Parliament already in 1985.

¹⁸² Recommendation R (88) 4 of the Committee of Ministers to member states on the responsibilities of health authorities in the field of blood transfusion (adopted on March 7, 1988).

¹⁸³ EEC Directive 89/381, 14 June 1989, in GUCE 28 June 1989, n.181 and GU 2^a Ss. 21 August 1989, n.65.

¹⁸⁴ Law 4 May 1990, n.107, in GU 11 May 1990, n.108.

¹⁸⁵ This principle is, after all, strongly rooted in the conscience of Italians. A 1994 survey carried out on behalf of the European Commission reveals that the overwhelming majority of Italians (88%) believes that blood donations should be completely free, as opposed to the 1% who accept the marketability of blood, Europeans and blood, in EUROBAROMETER 41.0, 1995.

give voice to the hemophilic and multi-transfused subjects organizations' right to participate to the institutional decision-making over blood and plasma safety.

Selling the *oro rosso* is now an *ad hoc* crime in Italy. Specific criminal punishments have been enforced to deter infringements of the regulations issued by the new Act. Whoever, by any means, profits economically from blood, or infringe the mandatory requirements described in the Act with regard to almost all the single phases of the transfusional activity is severely punished. A three-years maximum prison sentence is provided in this case, along with fines ranging from \$300 to \$15,000, while habitual offenders risk more severe punishment¹⁸⁶.

The Act also contains basic rules concerning donation requirements, donors features, and medical controls on donors, although -- as we shall see -- a wave of technical regulation concerning safety has been subsequently issued by Ministerial decrees.

The Productive Structure of the System

A soviet-like spirit of planning has been endorsed by the Act in order to enhance the productivity of the blood system¹⁸⁷. Words like "plan", "implementation", "coordination", "supervision" and a number of acronyms corresponding to a host of hierarchically organized bodies are impossible to avoid in describing the new structure of the Italian blood system.

The national transfusion system received a new organization chart made of Collection Units (CU), Transfusion Centers (TC) as well as Immunoematology and Transfusion Services (ITS). CU are fixed or mobile structures in charge of performing blood collection and plasmapheresis collection (CU), which are subjected to the technical supervision of TC, although they may be run directly by donors associations. TCs are established on a demographic ratio of one Center to every 150,000 inhabitants and carry out tests on donors, blood collection, blood typification, blood preservation, blood fractionation, blood allocation, and plasmapheresis; they also encourage self transfusion, guarantee the good use of blood, transmit collected plasma to the RCCCs coordinate CU, participate in epidemiological programs, and participate in educational programs encouraging blood donation among population. ITS are larger TC, established by a ratio of one Service to every 400,000 inhabitants or Province. Further to the TC tasks, they implement all measures aimed at evaluating and preventing post-transfusion diseases and, above all, viral diseases.

¹⁸⁶ Italian criminal law has already registered the first applications of these new provisions. In May 1996 the Director of a private clinic, who managed a system of recruitment of paid donors, was sentenced with 5 months of jail, E.VINCI, Scandalo sangue. Sanatrix condannata, La Repubblica, May 15, 1996.

¹⁸⁷ The Russian Alexander Bogdanov (1873-1928), the visionary founder of the Central Institute for Blood Transfusion of Moscow in 1926, would probably approve the new Italian regulations. Bogdanov, a prominent Bolshevik leader who was also a physician convinced of the rejuvenating powers of blood, theorized about transfusion efficiency. He intended to apply to blood the organizational principles developed under the name of "tektological laws" in his works *THE RED STAR* (1908), *TEKTOLOGY* (1912-1928) and *THE FIGHT FOR THE VITAL CAPACITY* (1928). He dreamed about a scientific society in which production is based on a system of instantaneous information on productive capacities and consumer demands. Screens would have indicated deficits and potential surpluses of production, and calculated pre-existing needs and available productive capacities. The Bogdanov's utopia was an ideal form of planning which permits the coordination of centralized and decentralized behaviors through the instantaneousness of information, see R.TARTARIN, *Transfusion sanguigne et immortalité chez Alexander Bogdanov*, 28 *Droit et Société* (1994), 565.

Regional Centers of Coordination and Compensation (RCCC), instead, implement and administer regional blood plans, with the task of filling the inter-regional gaps in the collection of blood and plasma. At a national level, the task of further coordinating the individual regional policies is assigned to ISS in Rome¹⁸⁸, which has also to express scientific opinions on the technical regulations issued by the Health Ministry upon the advice of the CNTA. As one can see, the Italian legislative attitude of creating hierarchical administrative bodies was not betrayed by the Act.

Also the voluntary donor organizations have been institutionalized by the reform. Their role as necessary mediators between health structures and general population has been fully acknowledged. But the Health Ministry now require them to abide their by-laws by a set of goals determined in a ministerial decree¹⁸⁹, as a necessary condition for being formally entitled to participate in the blood system. Regions are responsible for organizing local collecting activity by entering into special agreements with the donors organization. This negotiation is not unconstrained. Regional administrations must follow an uniform model of agreement set out by a Health Ministry decree, which provides for reimbursement to the organization proportionally to the quantity of blood supplied¹⁹⁰. This financial contribution is not intended as remuneration. Yet it is an obvious incentive for donor organizations (the more blood they supply, the more financial aid they receive to pursue their non-profit goal)¹⁹¹.

Planning and institutional coordination are the keywords for understanding the productive logic of the system, in the face of its sharp refusal of the market. This is especially true with regard to the reform's complex scheme of management for the collection and transformation process of plasma. In a non-economic setting, the scheme conceived in 1990 seeks to coordinate the three actors of the system: the no-profit organizations of voluntary donors, the public transfusion centers (with their functions not restricted to transfusion practice but extended to include the processing of blood -- plasmapheresis, fractionation etc.); the private producers of blood derivatives (deemed not replaceable by public plants, given the know-how and the financial means required by their highly specialized activity).

In short, the scheme is so conceived: plasma obtained directly by plasmapheresis¹⁹² in TC or by fractionation of whole blood collected by donors

¹⁸⁸ ISS has also other important tasks of control. It promotes researches in the immunotransfusion field, collects data on transfusion practice, inspects the private industry's plants where plasma is processed, and controls the quality of blood products.

¹⁸⁹ DM 7 June 1991 (in GU 26 June 1991, n.148).

¹⁹⁰ DM 18 September 1991, in GU 3 October 1991, n.232. The main guidelines of this ministerial pattern concern: the cooperation in promoting the culture of unpaid donation among the population; the coordination of donor recruitment in relation to the transfusion centers' needs; the exchange of information on donor suitability; the adoption of insurance coverage for damages incurred by donors (note: not recipients) as a consequence of donation; the operational standards of the ministerial regulations concerning donor safety.

¹⁹¹ This mechanism, based on the blood units supplied, boosts also the internal dynamics of the donor associations. In the AVIS national assembly the number of regional representatives is proportional to the number of donations obtained by each regional association. The same logic applies in regional and provincial assemblies.

¹⁹² F.BENCIVELLI, A.PIVI, R.CAMPI, *Plasmaferesi produttiva*, in *Il servizio trasfusionale*, 1991, 11, who reports the different psychological approach to plasmapheresis shown by voluntary donors, given their perception that the gift is not immediately to the benefit of the patient. This impression makes donors less inclined to undergo the procedure, since the altruistic choice is weakened by the interposition of an industrial process between the two subjects of the gift relationship.

associations, should be gathered at a regional level by RCCC, and then delivered to private industry plants of production authorized by the Ministry. This latter should then return the final products (AFC) to the Region's health structures, being paid on the basis of the liters of plasma processed. The raw plasma pertains to the regions even when this is processed, whereas the private company's payment is due solely for the processing performance.

Moreover, the reform regimented the choice of the private plants of production, renamed by the 1990 Act Blood Derivatives Production Centers (BDPC). Their number on the national territory is legally limited by a demographic ratio of one BDPC to every 20,000,000 inhabitants. Private companies willing to apply for authorization must meet precise requirements set out by law: the plant must be located in Italy, be technologically updated, be able to carry out the whole process of production in Italy, be able to produce albumin, third generation immunoglobulins, and AFC according to the latest scientific knowledge on viral safety.

Only in 1993, three years after enactment of the reform, a ministerial decree selected the two centers authorized to produce industrial blood derivatives in Italy¹⁹³. These centers have a legal monopoly for negotiating agreements for plasma/plasma-products exchange with the regional centers of plasma collection. Both the authorized plants, even if they apparently belong to different companies, were part of the same Italian pharmaceutical group (Marcucci group). The manifest limitation on free market entailed by this regulations has been ferociously contrasted by foreign pharmaceutical companies, which first challenged the Ministerial decree before the administrative courts and then promoted a consultative investigation by the Italian Competition Authority¹⁹⁴. In July 1996, however, the Marcucci group sold the companies owning the authorized plants to the Bayer pharmaceutical group.

Plasma Autarchy: Will the Goal Be Achieved?

The new rules of the Italian blood system seems to work well with regard to blood collection. In 1995 AVIS alone provided 1,415,288 units of whole blood, out of a total national need estimated at 2,400,000 units (source: AVIS Milan). Italy has almost achieved self-sufficiency in blood¹⁹⁵, although occasionally deficits still occur in the South¹⁹⁶. The gap between North and South may be overcome if the system manages to achieve a better level of coordination¹⁹⁷. Targeted advertising campaigns have been

¹⁹³ The authorization was issued by the DM 12 February 1993, in GU 20 February 1993, n.42

¹⁹⁴ In January 1996, the Authority concluded its investigation and, according to the Italian Antitrust law, transmitted a not-binding opinion to the Parliament on the opportunity to reform the 1990 Act. The opinion concluded that the limitation to competition entailed by the scrutinized regulations was not justified by safety considerations. On the contrary, this limitation had a counterproductive effect on safety, impeding the acquisition of better standard of quality which might be offered by competitors company. See, Italian Competition Authority notification January 26, 1996, *Attività di trasformazione del plasma*, available in Italian @ <http://www.agcm.it/italiano/segnal/as0065.html>.

¹⁹⁵ A.L.MASSARO, *Stato di attuazione della legge 107/90*, in 38 TS, 1993, 229, reporting a 15% deficit in Southern Regions.

¹⁹⁶ *Stanno finendo le scorte. Sangue, come prima, peggio di prima* [Supplies are to be used up. Blood, like before, worse than before], in *La Gazzetta del mezzogiorno*, 29 July 1996: reporting that in Apulia shortages of blood still occur when people goes on vacation.

¹⁹⁷ Despite the mechanism of compensatory token prices set up by the reform, Northern blood over-collection is not always able to reach the areas with a shortfall in their blood supply, U.BOLDINI,

recently planned by the Health minister in order to arouse public interest toward blood giving¹⁹⁸.

It is instead with regard to plasma self-sufficiency that the muddling regulations examined above has not given the desired results. The national supply of plasma is more than doubled since the 1990 Act, but is still far from achieving the total autarchy sought by reformers¹⁹⁹. The machinery for producing Italian AFC has encountered insurmountable obstacles in getting started, largely due to the bureaucratic logic endorsed by the reform²⁰⁰. Once again, technology seems to go faster than the laws: one may predict that the complex machinery set up for achieving the AFC autarchy will soon be made obsolete by the progressive wholesale availability of synthetic concentrates²⁰¹.

Viral Safety in the New Blood System

A step forward, at least when compared to the past legal framework, is instead the new legislative approach to technical regulations addressed to viral control. The past has counseled this time to the Parliament the express delegation of the power of introducing the rules of detail (for instance: new mandatory measures for blood testing, new screening and antiviral treatment, etc.) to the Health Ministry. These delicate measures are now to be introduced in the system by Decrees, replacing the negative practice of resorting to simple communications. This clear centralization of powers is an attempt to overcome the decision-making paralysis that gripped the previous system whenever rapid decisions were required in order to cope with a new viral threat or to introduce better and more up-to-date regulatory standards in the transfusion field (as for plasmapheresis or for blood bags)²⁰². It is pursuing this more flexible philosophy that in the last six years the Health Minister restlessly issued the detailed set of regulations that today forces the physician in charge of an Italian transfusion center to have the legal bulletin constantly at hand²⁰³.

This latter paradox stands for the fact that to date -- following the 1990 Reform -- the Health Ministry has enacted well nineteen decrees, which would be even more if all the scheduled regulations of detail were issued as envisaged by the Act itself.

The new rules for blood derivatives safety still rely on ministerial authorizations, but it is now specified that only for UE-member country can the national authorization be considered equivalent to Italian *ex-post* certification. A clear requirement is made

Evoluzione del servizio trasfusione e delle raccolte collettive di sangue, in *Il servizio trasfusionale*, 1992, 23.

¹⁹⁸ DM 1 September 1995, in GU 13 October 1995, n.240.

¹⁹⁹ On a national need estimated at 1,200,000 liters of plasma, the Italian fractionated plasma increased from 180.000 liters in 1992 to 400.000 in 1996. Yet, import of the two-third of the national need of plasma (either in form of AFC or semi-manufactured product) is estimated as for 1996 to cost approximately \$300 million (see, Italian competition, quoted above).

²⁰⁰ G.APRILI, G.MARCHIORI, Autosufficienza regionale nel settore degli emoderivati: l'esperienza veneta, in 38 TS, 1993, 238, reporting that restitution of AFC from the private plants is often delayed and criticizing the inefficient logic of the system, which forces each region to negotiate single agreements with the private plants, without having alternatives.

²⁰¹ The forum "The EC market in plasma products: a question of circulation" held in Brussels on April 1993 had already focused on this possibility. Starting from 1996 the Northern Region of Trento sustains the major cost of these new AFC for the sake of total safety of the local hemophiliac population.

²⁰² A.FLORES, Alcune considerazioni e riflessioni sulla legge n.107, in 36 TS, 1991, 674.

²⁰³ This is not a metaphor, but a personal testimony from an interview made to the head of the transfusion center of Trento.

concerning the need for batch-by-batch certification, both on the required test on the final product and on the testing of plasma donors. This certification on the negative results of the prescribed screening must be constantly available for inspection.

The new transfusion practice standard has been specified by two ministerial decrees²⁰⁴. Close attention is paid to donor selection. The (written) informed consent principle has been introduced in order to heighten the donors sense of responsibility and to ensure a more conscientious approach to the medical interview prior to donation²⁰⁵. The preventive testing of donors is made mandatory for: lues, HBaAG, HIV, HCV and HIV2²⁰⁶; while exclusion of donors who, although not resulting positive to the hepatitis marker test, has a medical history of jaundice is prescribed²⁰⁷.

How have the measures to date adopted and implemented in Italy reduced the HIV risk in blood transfusions? The available data show a progressive decline in the HIV-incidence rate on yearly tested donations from 0.029 (1985) to 0.004 (1994).

<i>Years</i>	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994
<i>Donations</i>	328,354	1,039,467	1,375,280	1,550,829	1,697,636	1,826,543	1,865,300	1,782,237	1,505,415	1,057,008
<i>HIV+ results</i>	95	287	199	185	193	142	111	102	93	41
<i>HIV incid. rate among donors</i>	0.029	0.028	0.014	0.012	0.011	0.008	0.006	0.006	0.006	0.004

Source: 13th Rapporto sul sistema di sorveglianza dello screening delle donazioni di sangue per anticorpi anti-HIV presso i centri trasfusionali italiani, Superior Health Institute -- Health Ministry, Rome 1995 (data reported for 1994 are not complete).

The same non-aggregated data report that the HIV-incidence rate is ten times higher among occasional donors than among periodic ones²⁰⁸, highlighting the crucial importance of promoting the spread of a well-established culture of gift among donors. The same source reveals that data on the factors of risk among HIV-positive donors show a decreasing rate of intravenous drug users (from 32.6% in 1985 to 4.9% in 1994), a slight increase in homosexuals (from 13.7% in 1985 to 19.5 in 1994) and a steady HIV-

²⁰⁴ DM 27 December 1990 (in GU 24 January 1991, n.20) "Features and standards for blood and plasma donation" and DM 15 January 1991 (in GU 24 January 1991, n.20) "Protocols for controls on the blood and plasma donors' fitness".

²⁰⁵ It is prescribed that during the interview physicians must inform the donors about the viral risks of transmission, thereby ensuring disclosure of information about possible previous infection with viral diseases like hepatitis. The same requirement applies with regard to HIV. The donor must read a leaflet which itemizes possible symptoms of the infection. Neither the questionnaire nor the leaflet make specific reference to homosexuality, while a general attention is paid to a possible sexual promiscuity of the donor.

²⁰⁶ HCV screening had already been made compulsory by the DM 21 July 1990, in GU 22 August 1990, n.195), while a subsequent decree did the same for the HIV2 virus in December 1992.

²⁰⁷ Concerning HTLV I/II virus, epidemiological studies among Italian blood donors have reported a very low prevalence (0.00651), see E.MANNELLA ET AL., Prevalenza dell'infezione da HTLV I/II nei donatori di sangue, in soggetti politrasfusi e in pazienti affetti da emopatie e neuropatie, in 38 TS, 1993, 123. These results have suggested that this further testing should not be made mandatory on Italian donors.

²⁰⁸ As late as 1991 the press denounced the high risk behavior of those giving blood in order to be tested for HIV; see C'è chi offre il sangue per avere un test riservato sull'AIDS, in CDS, 7 June 1991. Efforts to spread the message that anyone wishing can be freely and anonymously tested at public health facilities have eliminated this hazardous practice.

prevalence among apparently no-risk subjects (47.4% in 1985; 48.8 in 1994). Statistics of this kind ameliorate the predictive capacity of anamnestic precautions, but are unable to quantify the state of the risk (i.e. the likelihood of HIV-contamination for blood recipients). Therefore evaluation of the current Italian state of risk must rely on an estimation made by a 1990 study which calculated the likelihood of contamination by a whole blood unit testing negative on screening at a rate between 0.002% and 0005%²⁰⁹. Today this rate is surely much lower, given the progressive shortening of the window period due to constant improvements in screening techniques²¹⁰.

²⁰⁹ For this estimate, A.FLORES, L'infezione post-trasfusione da HIV: aspetti epidemiologici, diagnostico preventivi e riflessi medico legali, in RIML, 1990, 1075.

²¹⁰ The PCR methods is not standard practice in Italian transfusion centers, although experts have stressed for the importance of its mandatory adoption (compare, among others, the favorable opinion of the ISS Director: G.VICARI, La sicurezza fa un passo avanti, in Plasma & Derivati, n.3, 1995).