Chronology of the German AIDS scandal

by Jutta Dinkermann

The scandal actually began at a time when the HIV virus was still unknown. For hemophiliacs who were treated with coagulation separation products from donor blood and plasma, the greatest danger had always been that of being infected with hepatitis, since there was no way of killing these viruses. Then, in 1979, the Behring firm developed a heat-sterilized product in which hepatitis viruses (and also the AIDS virus, as it subsequently turned out) could be reliably destroyed. The disadvantage: The Behring products were approximately one-third more expensive than the non-sterilized, inert products.

From 1982 onward, after the Behring products were on the market (and thus at a time when HIV was being transmitted via blood products), it might have been expected that non-sterilized products would have immediately been declared illegal under existing medical laws, since practically all hemophiliacs had contracted hepatitis, which was the second most frequent cause of death in this patient group. Nonetheless, the Federal Health Office (BGA) issued no prohibition against non-sterilized coagulation products. A later, strenuous criminal proceeding against BGA president Überla and Prof. Manfred Steinbach, who was responsible for control of the BGA in the federal Health Ministry, was initiated in May 1990.

In December 1982, at least eight AIDS cases among hemophiliacs were known in the United States.

An article issued by the Robert Koch Institute reported in February 1983 that especially hemophiliac recipients of so-called Factor VIII coagulation products were becoming infected with AIDS.

In November 1983, there were further reports according to which heat deactivation with Factor VIII products had considerable importance in combatting risk of HIV infection for hemophiliacs.

In October 1984, specialists informed the BGA about the results of an international meeting of hematologists held in Rio de Janeiro in August of that same year. They reported that hemophiliacs treated exclusively with heat-treated products had not become infected with HIV, in contrast to those treated with conventional Factor VIII products, of whom 60% were infected.

In January 1985, experimental proof was presented that AIDS viruses are deactivated by heat treatment.

Although by January 1985, an HIV test was available to most firms, the BGA did not make HIV testing mandatory until October 1985. Moreover, the BGA neglected to recall untested blood products.

In October 1986, approximately 61 packages of a non-deactivated coagulation product (Factor IX) for hemophiliacs was put into circulation by the firm Organon. At least one person became infected. In December 1986, Behring reported to the BGA a case of a patient who had become infected from a non-deactivated PPSB process, a universal blood-coagulation method.

Only in July 1987 did a pharmaceutical protocol requiring deactivation go into effect—but, for unexplained reasons, only for Factor VIII products.

The firm Immuno immediately contacted Steinbach in the Ministry of Health about the risk of HIV infection through PPSB: "With hemophilia-B patients, products containing Factor IX have led . . . to an HIV antibody positivity to an almost equal extent as Factor VIII products. Additionally, in other clinical applications there may be . . . an unknown number of HIV infections as the result of Factor IX containing PPSB products."

In spite of the reference to "repeated cases" of HIV infection, the virus deactivation procedure continued to be prescribed only for Factor VIII products, and not Factor IX products and PPSB. Neither the ministry, nor the BGA saw any need for further action.

In 1990, eleven people treated with a "PPSB biotest" became infected with HIV. This could have been prevented, had the authorities checked into doubts about the effectiveness of cold sterilization. In August 1991, the Paul Ehrlich Institute certified that HIV viruses survive cold sterilization in the primary material.

Not until December 1991 was a deactivation process established for all non-Factor VIII products.

Playing fast and loose with blood

All experts already knew that the deactivation processes used showed great qualitative differences. Pasteurization at a minium of 60°C for at least 10 hours represents the "gold standard" for safety comparisons. Yet, up through the present, the BGA has treated all deactivation procedures as having equal quality.

Furthermore, what has long been the standard in veterinary medicine, as well as with serum and vaccines, is still lacking in blood production today: Batch control takes place only formally speaking, and there exists no program of thorough monitoring of the production by the BGA or an independent institution. A vaccine is subjected to expensive tests before being released; but a coagulation product is only given cursory inspection.

Also, limitation of pool sizes for coagulation products (that is, how many individual donors are used for a single batch) is a safety factor that has not been sufficiently heeded. For the producer, of course, large pools are more profitable. Theoretically, however, a single infected donor who remains unidentified despite HIV tests, could infect the entire pool.