

J-P Allain: last chapter, or merely latest?

"... science is a law-abiding profession. Less than 2 per cent of scientists have been imprisoned, exiled or executed, and nearly 33 per cent of those were French."¹

At times of public outrage, a system of justice is at its most vulnerable. Experience in the UK is illustrative. An IRA bomb explodes, killing several bystanders, and an Irishman is arrested. "The presumption of innocence, the right to silence, the right to legal representation, freedom from oppression and intimidation during questioning—the much trumpeted glories of our system of criminal justice—can too easily be reduced to nothing".² In France outrage at the use of HIV-contaminated blood in the mid-1980s has been extreme and the craven response of that country's system of prosecution and justice to that outrage has reached very dangerous levels. How often newspapers declaim that judges are out of touch with the common man—forgetting that at times the common man is vindictive.

On Jan 16, 1985, Dr Jean-Pierre Allain, head of research at the French national blood transfusion centre (CNTS) wrote to two senior people in the CNTS hierarchy warning them forcefully what HIV meant for that country's coagulation factor replacement therapy for haemophilia. He redoubled his efforts in March and April (his wife, Dr Helen Lee, did so too and was chastised by CNTS for her pains) and tried unsuccessfully to get *Le Matin* to show an interest.³ On June 1 of that year he and twenty-nine other French specialists in haemophilia, meeting at Pont à Mousson, drew up a list of recommendations, urging systematic screening of patients with haemophilia and their sexual partners and a programme of blood donor testing and viral inactivation for factor concentrates. They thought then that the risks of AIDS developing in an LAV(HIV) seropositive patient with haemophilia were low. (Documents from that period can be found as appendices to Allain's own story.⁴) Evidence of high seropositivity rates among French

patients with haemophilia receiving unheated local or US products⁵ was already widely known in haemophilia circles in that country. That high rate now seems to have been predictable, for France had long used prisoner blood donors, a policy that can hardly be laid at the door of the research arm of CNTS. At the time of which we speak, only a year or so after the identification of HIV as the probable cause of AIDS, there was uncertainty about many things—were HIV antibodies protective, would heat treatment really work and might it carry a penalty in inhibitor development, and were the tests reliable enough, for instance?

Peering down the retrospectroscope it is easy to claim that preventive actions could and should have been taken earlier—indeed such claims have been made in many countries—but in France matters got out of hand. Compensation was not enough. A guillotine had been sharpened and it was merely a question of finding personnel for the tumbril. Not the politicians, not then anyway.⁶ The prosecution has cheerfully conceded that it could have been anyone from hundreds; in the event it was Allain, with Dr Michel Garretta from CNTS, and two others. A key factor in this miserable tale was the charge, which was based on an archaic piece of legislation that offered a major advantage for the prosecution—namely, that no panel of medical experts would be able to assist those hearing the cases ("Nous aurions autrement suicidé notre procédure avant même de commencer!").⁷

Those trials took place in 1992, and *The Lancet* has recorded one sorry chapter after another, including appeals that turned out to be retrials.⁸⁻¹⁰ The latest development¹⁰ carries within it grounds for optimism simply because it is so ghastly. First Garretta and then Allain have been brought before a judge for examination on a new, and more serious, charge—that of wilful poisoning. So why be hopeful? For one thing the outrage among physicians and scientists is now shared by lawyers

and senior magistrates in France. The concept of double jeopardy is as alien to the French as it is to others. The European Convention on Human Rights has a protocol banning such prosecutions, and the president of the French Supreme Court, on television of Aug 10, expressed his opposition to a retrial. Furthermore, on the assessment of the French press, the judge is independent and fair; and she is a specialist in medical cases, having under her wing the growth hormone/Creutzfeldt-Jakob investigation as well as the Garretta and Allain poisoning allegations. The French press is beginning to produce more balanced and critical accounts. And this time, if the matter were to come to trial, there would be an expert panel. Judge Odile Bertella-Geffroy has before her a controversial dossier, and her decision will affect more than the liberty of Allain and Garretta. The threat of interrogation on a charge of wilful poisoning

hangs over many physicians, not just those whose names have so far been associated with this non-crime.

The Lancet

- 1 Hawkes N. How to carry off the Nobel prize. *Times* July 28, 1994.
- 2 Bennett R. Double jeopardy: the retrial of the Guildford Four. London: Penguin Books, 1993.
- 3 Statement by the Royal College of Pathologists on the matter of Professor Jean-Pierre Allain: 19 November, 1993. *Bull R Coll Pathol* 1993; 84: 3-4.
- 4 Allain J-P. Le sida des hémophiles: mon témoignage. Paris: Éditions Frison-Roche, 1993: annexes 1-35.
- 5 AIDS-Hemophilia French Study Group. Immunologic and virologic studies of multi-transfused patients: role of type and origin of blood products. *Blood* 1985; 66: 896-901.
- 6 Nau J-Y. French ministers to be charged for blood scandal. *Lancet* 1994; 344: 256.
- 7 Greilsamer L. Le procès du sang contaminé. Paris: Le Monde Édition 1992: 94.
- 8 Editorial. Palais d'injustice. *Lancet* 1993; 342: 188.
- 9 Brahm D. Trial and tribulations of J-P Allain. *Lancet* 1993; 342: 231.
- 10 Sharp D. l'affaire Allain. *Lancet* 1994; 344: 467.

Proposal quality or product quality?

The National Institutes of Health (NIH) in Bethesda, USA, spends \$8 000 000 000 a year on grants, making it the largest biomedical research granting body in the world. The remarkable growth and great success of this organisation since World War II have been based on its investigator-initiated peer-reviewed grants system. Initially the review committees amounted to a roll-call of the elite of the American research establishment, but in recent years they have become egalitarian; young scientists have been coopted and a correct social balance has been established. The system is such that virtually all the vast number of massively detailed investigator-initiated RO1 grant proposals submitted each year (19 072 in 1993) undergo complete peer review and virtually none is rejected; they are either approved and funded or approved but not funded. One reason for this strategy is that, whereas rejection can lead to confrontation or litigation, unfunded approval is less likely to do so. However, this ploy gives the impression that almost all grants sent to NIH are worthy of funding, that the small proportion of RO1s that are funded (about 20%) must perforce be splendid, and that something must be done about the myriad of excellent but unfunded researchers. Several questions arise. First, do the fortunate grant recipients regularly produce quality products? Second, could the money available, if spent in different ways, provide more and better products? Third, is additional money necessary?

The recent ferment in grant-making at NIH has been closely observed by the biomedical research community. One initiative is triage of investigator-

initiated grants to remove about 50% from the enormously labour-intensive review system.¹ The immediate implication of that decision is that a large percentage of RO1 grant proposals are now deemed to be of insufficient quality to be considered for funding. A round-table meeting of scientists from across the USA discussed some innovative ideas. "Chunk grants", which provide a fixed sum so that a proposal can be focused on science rather than on budgets, were warmly received. The most exciting concept, however, was a change from prospective evaluation of grant proposals to retrospective evaluation of the applicant's previous research. While this idea elicited objections about women and minorities, and worries about "old boys", reasonable compromise would be to provide for both prospective-based and retrospective-based grants, which could be allocated among the grant applicants for whom they are most appropriate. Those with excellent and ongoing track record would qualify for the retrospective approach, whereas younger researchers would be eligible for the prospective system.

Two suggestions that might help NIH in its search for ways to improve the efficiency and effectiveness of its grant-making systems are (a) evaluation of the products of its present investigator-initiated peer-reviewed system (as far as one can determine this is not done systematically) and (b) consideration of grant-making mechanisms used by other organisations that support biomedical research.

Outcome analysis is all the rage in the delivery of health care. By comparison, medical research is