AIDS Fears Spark Row Over Vaccine

Paris. Growing public concern in France about the spread of acquired immune deficiency syndrome (AIDS) is threatening the health of what appears, at least so far, to be an innocent victim—French efforts to promote foreign sales of a vaccine against hepatitis B. The vaccine is produced by the Institut Pasteur Production (IPP), a private company owned 51 percent by a subsidiary of the nationalized oil company Elf Acquitaine and 49 percent by the Institut Pasteur in Paris.

Last week, the president of IPP, Yves Garnier, filed suit against the Paris-based newspaper *Liberation* over a series of articles which appeared at the end of June raising questions about the safety of IPP's vaccine. The articles concentrated in particular on the company's use of American blood plasma, which is mixed with plasma from European sources, to produce the vaccine. They raised the possibility that, since AIDS is thought to be transmitted by some blood products, the vaccine could become a carrier for the disease.

While admitting that this theoretical possibility exists, IPP nevertheless maintains that each batch of its hepatitis B vaccine has been carefully checked for the presence of both viruses and retroviruses (and is now being double checked by government inspectors) and that no such problem has been discovered. The company claims the newspaper's articles have unnecessarily stirred up public concern about the safety of a vaccine which has been widely and safely used since its introduction 2 years ago. It has expressed particular anger over a front page headline "Pasteur Institut Suffers from Gay Cancer," and is demanding 1 million francs (about $140,000) in damages.

French medical journalists have, in turn, accused the company of excessive secrecy over the procedures followed in the production of the vaccine. They point, for example, to the fact that the Ministry of Health was not initially informed about the use of the American plasma in the production of some batches of the vaccine, and that the company appears to be out of step with a recommendation from the Council of Europe concerning the prevention of AIDS, which suggests the avoidance, whenever possible, of "the import of blood products from countries where the payment of blood donors considerably increases the risk of contamination."

The controversy has come at a particularly sensitive time for IPP, since it is locked in intense competition for foreign sales, especially to Third World countries, with Merck Sharp & Dohme, whose hepatitis B vaccine is produced by a different process. Already several countries have decided in favor of the American vaccine.

Scientists at the Pasteur Institut are no less happy than IPP with the way the controversy has blown up in the French press, and in particular over the way that questions about their research have been raised by the action of what is, formally, a separate company.

Following the appearance of the *Liberation* articles, the institute took the almost unprecedented step of calling a press conference to deny charges of impropriety, issuing a strongly worded warning against journalists spreading anxiety among the public "on the basis of fragmentary information," throwing discredit on research institutes and on French biological research "by questioning their methods and their integrity," and planting unfounded doubts about the quality of a vaccine, thereby threatening "the success of a French industry whose revenues go primarily to research."

The controversy is particularly ironic for scientists at Pasteur because some of them are deeply involved in identifying the possible causes of AIDS. In particular, the group headed by virologist Luc Montagnier earlier this year identified a retrovirus that had been isolated from the T cells of a homosexual male with the symptoms that often precede AIDS (*Science*, 20 May 1983, p. 868).

At the time, the Pasteur discovery seemed to support a general hypothesis being developed in several U.S. laboratories that AIDS might be caused by the human T cell leukemia virus (HTLV), based on evidence of HTLV infection in patients who have either contracted or were at high risk for the syndrome. (There is, however, some debate over whether HTLV infection is a cause or a symptom of AIDS.) More recently, says Montagnier, other properties of the virus isolated by the Pasteur group indicate that it may not be as similar to the conventional HTLV virus as was originally thought—a finding which could lead to significant new developments in understanding the etiology of the syndrome.

France has also been at the forefront of attempts to understand the epidemiology of AIDS in Europe. Soon after the first reports from the U.S. Centers for Disease Control in 1981, an informal group of interested physicians and researchers in Paris rapidly started gathering data on its incidence in France (still relatively low, with about 60 known cases) and speculating about its possible pathology.

As formal recognition of the AIDS problem began to grow, a high level working group was established by the Ministry of Industry and Research to support more intensive studies, in particular of the epidemiology of the disease. Several major laboratories in France have now expressed an interest in participating in this research, while at the European level a meeting is being held in Denmark next month to coordinate approaches toward the detection and characterization of AIDS, the appropriate treatment for sufferers, and the research needed to study its epidemiological aspects.

As for research into the virus itself, the French researchers are now turning—for reasons of both time and the availability of facilities—to the U.S. National Cancer Institute for assistance in cloning the virus they have discovered so that its properties can be carefully studied.

Montagnier suggests this is a "very good example" of international collaboration in research, given the substantially higher level of resources currently available for such research in the United States. Phillipe Lazar, director-general of the National Institute of Health and Medical Research (INSERM), admitted last week that the "academicism" which tends to dominate the French approach to the support of research sometimes made it difficult to respond with "the intensity and the rapidity" that a particular problem—such as quickly determining the characteristics of a virus potentially associated with AIDS—might require.—**DAVID DICKSON**