Japan settles HIV-tainted blood cases

The Japanese government and five pharmaceutical companies have finally agreed to compensate hundreds of Japanese hemophiliacs who were infected with human immunodeficiency virus (HIV) in the 1980s after using non-heat-treated blood products. This brings an urgently needed settlement to a legal battle that has dragged on for seven years. Many questions, however, remain about how this disaster was allowed to happen in the first place, prompting the beginning of a criminal investigation.

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Executives of Green Cross Corporation, which held 50 percent of the market share of untreated blood products in 1983, apologizing publicly to the plaintiffs.

The out-of-court settlement was signed after a final settlement plan was proposed by the Tokyo and Osaka district courts, and after the government and companies apologized to the victims. The five pharmaceutical companies and the government will pay each plaintiff a lump sum of 45 million yen (US$450,000) now, and 150,000 yen (US$1,500) a month after they develop AIDS. The companies (Green Cross Corp., Bayer Yakuhin Ltd., Baxter Ltd., Nippon Zoki Pharmaceutical Co., and Chemo Sero Therapeutic Research Institute of Tokyo) will pay 60 percent in proportion to their market share of untreated blood products in 1983, and the government will pay the remaining forty percent.

The Japanese government has also agreed to set up two urgently needed national AIDS research and treatment centers in Tokyo, one at the International Medical Center of Japan and the other at the National Institute of Health. The centers will conduct research on new treatments and perform clinical trials, as well as provide HIV training for other hospitals. Ministry of health officials are planning to link the centers by computer to 182 hospitals throughout Japan that have recently been designated as AIDS treatment centers. However, the money for these plans has not yet been allocated.

The historic settlement comes only a month after Japan's new Minister for Health and Welfare, Naoto Kan, apologized publicly, acknowledging that the ministry was partly responsible for failing to prevent the infections. Immediately after his appointment in January, Kan, a former civic activist, set up an AIDS task force. Previously "non-existent" ministry documents were soon discovered showing that the ministry was aware, in 1983, that the infectious agent causing AIDS is transmitted through blood and other body fluids, something the ministry earlier refused to admit. Other recently released documents show that, in July 1983, the ministry considered importing heat-treated blood coagulants from the United States as an emergency measure, but rejected the idea a week later, allegedly to protect the domestic blood products industry. The importation of heat-treated products was approved by the Ministry two years later. In the interim, thousands of hemophiliacs were infected with HIV.

This is the first time the Japanese government has admitted responsibility in a drug side-effects case, according to Toshihiro Suzuki, a lawyer representing the plaintiffs in Tokyo. Despite public apologies from the Minister, there is still some debate as to whether the Japanese government has actually admitted that it was negligent, and ministry officials are unwilling to clarify the issue. "The final wording of the settlement agreement was not perfect and does leave some room open for legal discourse," Suzuki says.

Attention is now being focused on the individuals involved. A few days before the settlement was signed, the Tokyo District Prosecutors office set up a team of six prosecutors to investigate possible criminal charges. Accusations of criminal liability and perjury have already been filed against former officials, and in February the mother of a victim filed an accusation of murder with the Tokyo District Prosecutors office against Takeshi Abe, a central figure in the scandal (Abe headed the ministry's AIDS study group that advised the continued use of non-heated blood products in 1983).

Notwithstanding the enormity of the problem, critics of the government argue that this scandal is by no means unique. "This case is not exceptional," says Masanori Fukushima of the Aichi Cancer Center in Nagoya, "it reflects the deep rooted problems with the mechanism of drug approval in Japan." Fukushima, a longtime campaigner for reform of Japan's drug approval system (*Nature Medicine* 1, 13; 1995), believes this is an unprecedented opportunity to look at the system with a view to change. He is not, however, optimistic about the chances for sweeping reform. But calls for reform are increasing. "Collusion among the Ministry of Health and Welfare, drug companies, and doctors must be ended to prevent a repetition of this kind of tragedy," wrote the editors of Mainichi Shimbun, one of Japan's leading national newspapers, in a recent editorial.

Kan has promised to look into the possibility of broad-reaching reforms of both the drug approval system and the ministry's pharmaceutical affairs bureau. However, any reforms are likely to be incremental. It is questionable whether the necessary extra funding to improve the system will be available at a time when Japan is desperately trying to reduce the amount it spends on health care (*Nature Medicine* 1, 985; 1995). Furthermore, the Ministry is very reluctant to make far-reaching reforms. "Reforms could endanger the nation's health," says one Ministry official, pointing out that the word for drug '*kusuri*' in Japanese when read backwards reads as risk (*risuku*), implying the belief that a cautious approach to reform is needed.

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