Facing up to Japan's Dark Side

By Catrien Ross

On March 14, top executives of Green Cross Corp., an Osaka–based pharmaceutical company, were photographed kneeling low to the ground in a show of apology. Four other drug firms also apologized: Bayer Yakuhin and Nippon Zoki of Osaka; Baxter Ltd. of Tokyo; and Sero Therapeutic Research Institute of Kumamoto.

The melodramatic gesture signaled the ending of a seven–year–long legal battle with hemophiliacs who became infected with HIV through tainted blood products distributed by the five drug firms in the early 1980s. The callousness of actions that blatantly put profits before patient safety has outraged many Japanese, who are equally angered by the widely perceived collusion of the Ministry of Health and Welfare (MHW). The government had continued to allow the import of unheated blood products for two years after the risk was known. On March 15, MHW Minister Kan Naoto issued a government apology to HIV–infected hemophiliacs and announced the government's decision to accept a court–proposed compromise for compensation. More than 400 hemophiliacs in Tokyo and Osaka had filed suit against the government and the five drug companies. In a clear censure of the state, the courts had recommended that the government shoulder 40% of the compensation, with 60% to be borne by the pharmaceutical companies according to the portion of market share held at the time tainted blood products were sold. Of an estimated 4,000 to 5,000 hemophiliacs in Japan, at least 1,800 have contracted HIV, some 580 have developed AIDS, and about 400 have died.

Meantime, accusations of murder have been filed against Abe Takeshi, the doctor who headed the government's AIDS research team set up in 1983. Abe has also been criticized for accepting at least ¥43 million in donations from the five drug firms. In another first for Japan, a murder charge has been leveled at Matsushita Renza, a former chief of MHW's Pharmaceutical Affairs Bureau who, after retirement, became president of Green Cross Corp.

Now that all HIV–infected plaintiffs have agreed to the terms set out in the court compromise, the legal battle for financial compensation has officially ended. But many questions remain. The most troubling concern the accountability of the Ministry of Health and Welfare, which mysteriously "lost" key files and hid other pertinent information. Many are asking why the ministry, which is supposedly responsible for overseeing public health, should have acted with such negligence concerning

Photo: Kyodo News Service

Green Cross Corp., president and others bow in apology after agreeing to the second settlement for HIV plaintiffs.

Japan's blood supply.

Changing Assumptions

Almost daily media coverage of the blood products scandal has prompted an increasing number of Japanese people to more closely scrutinize the role of the MHW and the motives of drug companies. But a look at the history of the relationship between the pharmaceutical industry and government officials shows that this is not the first time that such a scandal has occurred. As Japanese are more and more discovering, it is naive to assume that drug firms have the best interests of the patients at heart. As a big business their primary concern is profits. On the other hand, citizens have a right to expect that the Ministry of Health and Welfare will check and curb unethical business practices that may harm the very taxpayers who have placed their trust in government responsibility.

Unfortunately, as several critics have pointed out, there exists a too cosy relationship between the ministry and drug firms, as well as between drug firms and doctors conducting clinical trials. A major problem is how retiring senior health officials can look forward to cushy jobs in the private sector. Known as *amakudari*, or "descent from heaven," this practice, common to Japan's major ministries, ensures that bureaucrats will be well looked after by the same companies they regulated and checked while in office. Early in 1994, for example, a Tokyo–based private think tank on medical issues examined Japan's drug research procedures and concluded that of the 3,100 new drugs approved in Japan over the past 20 years only 49, or less than 2%, are effective according to U.S. Food and Drug Administration criteria. The findings may have much to do with too close ties between drug firms and MHW, particularly the Pharmaceutical Affairs Bureau. An estimated 100 high–ranking officials of this bureau have become advisers or executives of drug companies. Although the Pharmaceutical Affairs Law requires the state to provide safe drugs, the reality is that health officials do not take individual responsibility for negligence or administrative failures. After the ministry became aware of HIV–infections caused by blood products, several officials took executive jobs at Green Cross Corp., which critics likened to a detached office of the Pharmaceutical Affairs Bureau.

In 1994, in the wake of 16 deaths caused by sorivudine, a drug marketed by Nippon Shoji to test herpes zoster, the MHW set up a study group to revise the procedures for testing and approving new pharmaceuticals. In Japan, pharmaceutical companies not only select the doctors to conduct pre–licensing clinical trials for a drug, but also have the data scrutinized by a senior doctor appointed by them. Two years ago the Japan Pharmaceutical Manufacturers Association launched guidelines aimed at eliminating corruption involving doctors and drug companies. Large amounts of money have been routinely given doctors conducting clinical trials, ostensibly to promote the claims of drugs under development. Doctors, too, have solicited considerable sums of money from pharmaceutical companies where clinical test results can determine success or failure of a drug under research and development. Before a new drug is approved for use in Japan, the Central Pharmaceutical Affairs Council (within the Ministry of Health and Welfare) must examine results of toxicity tests, animal tests, and clinical trials. All these tests are done at universities or research organizations at the request of pharmaceutical companies—one explanation why research commissions have appeared prominently in bribery cases.

Last year I met with Goto Takanori, an impassioned lawyer who has represented both victims of industrial pollution–caused Minamata disease and victims of the side–effects of chloroquine. In a court case begun in 1975, 100 actual victims, along with 170 next–of–kin, sued the central government, six pharmaceutical companies and doctors who prescribed chloroquine after 1970 notwithstanding side–effect warnings. Chloroquine became a non–prescription drug in Japan around 1955 and it is uncertain when the Ministry of Health and Welfare first learned about associated retinopathy, an eye disease for which there is no cure and which eventually leads to blindness. But at least one drug company had submitted such a report by early 1965.

At that time the chairman of the drug industry's safety committee reported side–effects to the head of MHW's Drug Safety Section, Toyoda Kinji, who was taking chloroquine for rheumatism. During the first trial, in 1978, Toyoda testified that he had immediately stopped taking the drug but had neither warned the public about side–effects, nor investigated the extent of damage in Japan, where chloroquine had been mass–marketed since 1961 as a drug treatment for nephritis (inflammation of the kidneys), but was also used for epilepsy and atopic dermatitis. In 1967 Toyoda finally designated it a prescription drug, citing toxicity, but changes in drug instruction inserts warning of eye damage were not ordered until 1970. Goto believes that if Toyoda, had, at the first moment he personally learned of side–effects, banned the drug and pulled it off the market, then 80% of the eventual victims would have been spared. After retirement Toyoda became an executive board member of Tokyo Pharmaceutical Industry Association.

In fact, in Japan, there has been a continuing pattern of drug–caused damage that some experts say was spotlighted in 1962, the year the so–called Thalidomide Case became known. There had been several instances of damage as a result of drugs before that, but the exposure of side–effects due to thalidomide did much to raise public and government awareness. The sight of severely deformed babies had considerable impact in warning about the use of drugs.

Japan's worst drug–related disaster was so huge that it is considered the largest of its kind in the world. The so–called SMON (subacute myelo–optic neuropathy) side–effect that occurred in the 1960s and 70s, was caused by the drug chinoform, which was widely sold in Japan for diarrhea. An MHW research team confirmed at least 11,000 victims, although unofficial estimates are much higher.

The recent scandal involving tainted blood products repeated a pattern that Goto says is typical of drug–damage in Japan. First, initially both the drug companies and the government reject claims of victims and up to the last moment deny any responsibility. Second, whereas in other countries criminal cases are brought, in Japan the only legal action is limited to litigation initiated by the victims. In France, for example, the problem of tainted blood products precipitated a national scandal that destroyed careers and even contributed to the defeat of a government. Senior public health officials were accused of knowingly allowing contaminated blood to be given to hemophiliacs. Some of these officials were convicted and either jailed or given suspended sentences for fraud, criminal negligence, and failure to assist persons in danger. In Japan a similar situation at first fueled little or no public outrage. Third, in Japan drug companies consider recalling a drug only after the side–effects are widely reported in the mass media.

Profits over care

Despite a continuing pattern of drug–damage, most people, out of apathy or ignorance, continue to overlook the fact that the medical system in Japan is flawed by an emphasis on profits over quality and safety of health care. The fact that the Japanese lead the developed world in per capita prescription drug consumption is a testament to the power of the drug industry and the trust people have in the doctors who prescribe them.

Yet such blind trust should be carefully reexamined. Doctors in Japan are known for over–prescribing medication for their patients. When the Western system of medicine was introduced into Japan at the start of the Meiji Era in 1868, doctors were allowed to sell their own drugs. In effect they have been drug sellers. The National Health Insurance system introduced in 1960 allowed doctors to be paid at the prices for medical services approved in the Official Price List set by the Ministry of Health and Welfare. Although the purpose of the scheme was to limit government costs for health care, the actual result was that pharmaceutical suppliers began offering discounts on drugs named in the Official Price List as an incentive for doctors to prescribe them. Since doctors can be reimbursed by the government at the listed price, the difference between the discounted price and the Official Price List has been a source of profit for the medical profession. Small wonder then, that doctors in private practice buy most of the Rolls Royce cars sold in Japan, if what one car dealer told me is true.

At the same time, information concerning drugs and potential side effects is rigorously controlled by the pharmaceutical industry, which has actually concealed unfavorable facts. In addition, many doctors are so busy—the average length of a patient visit is three minutes—that few have the time to monitor pertinent medical journal information relating to drugs and their side effects. Most doctors receive their information about drugs from the sales representatives sent by drug companies. All of this means that responsibility for personal health and medical system decisions must increasingly lie with the consumer, the patient. And it is precisely in this area that Japan lags behind the United States or Europe, where patients are much more willing to assume an active role in the treatment process. In Japan it is the rare patient who dares to question the perceived authority of the doctor: the patient–doctor relationship is highly unequal.

An example of this is doctor disclosure of cancer. It remains common practice in Japan for doctors not to disclose information about cancer to patients, although the immediate family is often told. A survey released by the Ministry of Health and Welfare last May revealed that only one in five cancer patients who died from cancer the previous year were informed about their disease. The survey also showed doctor reluctance to discuss cancer therapy: only 43.7% of patients were given any details of their treatment. For terminally ill patients, the doctor or family alone, or both together, decided on therapy for about 70% of patients. Patients were themselves consulted about the choice of therapy in only 16.2% of cases. Nor is this situation likely to change very soon. The first legal judgement on a doctor's responsibility to tell cancer patients about their disease was passed last April, when the Supreme Court pronounced that doctors are not obliged to inform patients with cancer about their condition, upholding earlier rulings by district and high courts.*

Indeed the whole idea of informed consent is a new concept in Japan, which has no Japanese language translation of the term. Japanese doctors are currently recommended but not required to obtain the informed consent of patients concerning medication and treatment. In the worst instances of abuse this has led to patients being used as guinea pigs for drugs or medical procedures such as surgical operations. In Japan, patient rights have largely been ignored.

The fact that such a situation exists is directly linked to a post–war government policy that has placed administrative priority on an economic efficiency meant to catch up to or overtake Western nations. But the economic boom has generated what Goto calls the dark side to progress, including pharmaceutical victims and a medical system that encourages abuse. People have been continuously sacrificed for the sake of company profits.

Unless there is a complete overhaul of social and administrative structures, however, there is little likelihood that priorities will ever change. The Ministry of Health and Welfare will continue to look out for the drug companies who in turn will look only to their bottom line and the doctors who can maintain it. Japanese people, meantime, will continue to suffer and die. JJTI

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