

Chapter 9

Promotion of Measures for Safety and Security of People

Section 1. Responding to Hepatitis C Lawsuit

1. Outline of Hepatitis C Lawsuit

(1) From Filing Lawsuits to enactment of Bill and Compromise

Compensation Lawsuits were filed in 5 district courts (Tokyo, Osaka, Fukuoka, Sendai, and Nagoya) against the government and drug manufacturers over Hepatitis C virus infections caused by fibrinogen or coagulation factor IX products tainted with Hepatitis C virus, blood products to stop hemorrhaging in the deliveries, over the period of 1971 to 1990. The judgments of 5 district courts were rendered over the period of June 2006 to September 2007.

Each district court judgment differed in the period for which drug manufacturers and the government were liable and the type of drug products. The defendants and the plaintiff then discussed the compromise recommended by the Osaka High Court. As the final result, “Law concerning Special Measures to the Payment of Benefits to Relief Sufferers from Hepatitis C Infection caused by Specific Fibrinogen Products and Specific Coagulation Factor IX Blood Products” was enacted on January 11, 2008 to provide uniform relief regardless of the period of administration. The Preamble to the law is as follows:

The Preamble to the Law concerning Special Measures to the Payment of Benefits to Relief sufferers from Hepatitis C Infection caused by Specific Fibrinogen Products and Specific Coagulation Factor IX Blood Products

Hepatitis C virus infection caused by Hepatitis C virus – tainted blood products, fibrinogen products and Coagulation Factor IX blood products has inflicted both physical and mental pain on the sufferers and their bereaved families for a long period of time.

The government shall recognize its liability that it caused the great damage to the sufferers and could not prevent its spread, and offer sincere apologies to both them and their bereaved families.

Furthermore, reflecting on this incident the government shall realize the importance of people’s lives again and make the maximum effort to prevent any recurrence of suffering to people’s health caused by drugs.

Essentially, drug distributor are obliged to make the best effort in ensuring the safety of their products and accused of being liable in this case.

The sufferers from Hepatitis C virus infection have filed compensation lawsuits against the drug manufacturer that produced fibrinogen products and Coagulation Factor IX blood products and the government. The judgments of 5 district courts differed in accordance with the period when

drug manufacturer and the government were liable. The resolution through lawsuits disputing over legal liability under current legislation is expected to take a long period of time.

Generally, appropriate use of blood products is essential in saving people's lives. We think of that the people infected by Hepatitis C virus through fibrinogen products and Coagulation Factor IX blood products face the anxiety over their symptom becoming more serious with their daily lives. From a humanitarian point of view, we shall provide uniform relief immediately regardless of the period of administration. However, there are limitations both judicially and administratively with fulfilling requests for uniform relief from the sufferers of infection. And hence the law was enacted to offer legislative resolution.

In accordance with the law, the government recognized its liability for that it caused great damage to the sufferers and could not prevent its spread, and offered sincere apologies to them and their bereaved families, and made a promise to make the maximum effort to prevent any recurrence of suffering to people's health caused by drugs by a basic agreement signed by the Minister of Health, Labour and Welfare, the plaintiff, and the counsel on January 15, 2008.

In addition, the first compromises were concluded at the Osaka High Court and Fukuoka High Court on February 4, 2008.

The Ministry of Health, Labour and Welfare is making an effort to publicize the concept of the law as well as calling for people to take Hepatitis virus examinations who were possibly administered fibrinogen products or Coagulation Factor IX blood products through disclosing the names of the medical institutions that the products were supplied to. Efforts are also being made to facilitate compromise with the sufferers of the Hepatitis C virus infection caused by administration of specific products in accordance with a payment system based on the said law after that the actual administration was proved by courts.

In addition, "Study Group on Examination of Hepatitis C virus infection caused by using of Hepatitis C virus-tainted blood products and Prevention of the Recurrence" since May 2008 is held with the aim of a third party examining the incident, as provided in the basic agreement, and to make suggestions about considering pharmaceutical administration for preventing recurrence.

(2) Issue of Fibrinogen Data

Data, including a table of 418 cases related to the administration of fibrinogen products, submitted by Mitsubishi Pharma Corporation (at the time) in response to an order to submit a report was published with masking (private information painted black) in 2002. The Ministry of Health, Labour and Welfare, however, discovered data with the names of 2 patients that had not been masked in basement storage on October 19, 2007.

The Minister of Health, Labour and Welfare ordered an investigation of this issue and its

background. The “Project Team for Investigation on the Fibrinogen Data Issue and its Background” (hereinafter referred to as the “Investigation Team”) conducted investigations and published the results on November 30, 2007.

The data with no masking consists of cases in which adverse drug reactions had taken place and were collected from medical institutions by Mitsubishi Pharma Corporation (at the time). The investigation revealed that after the data had been submitted by Mitsubishi Pharma in 2002, it was stored in a basement without having been appropriately transferred to successors. The transfer/management of the data was quite inappropriate in such that acceptance of the data had not even been recorded in the relevant document registration book. In addition, no discussions were made within the Ministry on notifying the 418 patients by identifying the individuals using the data. The Investigation Team reported that since the Ministry failed to think about notify the patients, “as an organization in charge of issues concerning people’s lives and health, the Ministry should accept the serious criticism in its entirety, that the Ministry should realize what should be done for people suffering with Hepatitis from the viewpoint of the patients”.

In response to this report, the Ministry of Health, Labour and Welfare is making the effort to appropriately manage documents within the Ministry that includes thorough directions on appropriate storage/management of administrative documents. In addition, the Ministry is making their best effort with measures where people can take examination/treatment for Hepatitis as early as possible through disclosing the names of the medical institutions that fibrinogen products and Coagulation Factor IX blood products were supplied to, as described earlier.

2. HIV/CJD Problems and Reflections on Damage to Health by Drugs/Medical Devices

(1) Compromises and Confirming letters Concerning Lawsuits Regarding HIV Problem and CJD Problem

Hemophiliacs had filed compensation lawsuits for damages arising from HIV infections caused by blood products against the government, drug manufacturers and these compromises were concluded on March 29, 1996. And sufferers who had infected by CJD through human dry dura known as “Lyodura” had filed compensation lawsuits for damages against the government, drug manufacturers. A compromise of these lawsuits was concluded on March 25, 2002.

In confirming letters concerning these compromises, Ministry of Health, Labour and Welfare had stated that it would sincerely and seriously accept the views of the court. Furthermore, it realized the serious responsibility of the Ministry for the spread of HIV infection among hemophiliacs and the CJD infection that resulted from the transplantation of the human dry dura of “Lyodura”, as well as for the terrible harm that resulted, which was pointed out in the letters. It also

stated that the Ministry wholeheartedly apologized to the sufferers, including the plaintiffs having serious mental and physical damage, and the fact that they had been forced into an extremely serious situation.

Ministry of Health, Labour and Welfare then made a firm promise to make an effort to investigate the cause of these incidents and to confirm what improvements had been made. It also made a promise that Ministry of Health, Labour and Welfare would make the best efforts to prevent any recurrence of suffering to people's health caused by drugs, based on the recognition of their great responsibility to provide safe and effective drugs to the people and to protect people's lives and health from adverse drug effects and adulterated drugs.

(2) Promotion of Various Permanent Measures

Ministry of Health, Labour and Welfare is taking the following permanent measures that were based upon compromises reached in the HIV and CJD lawsuits.

1) Upgrading of medical care system

The Center for AIDS treatment, Research and Development was founded at the International Medical Center of Japan with the aiming of improving medical care standards for AIDS in respective regions and to correct any regional differences. In addition, regional-block core hospitals were established in 8 districts, which are there to secure the appropriate medical treatment, along with model hospitals for AIDS treatment. In the mean time, a system to send at-home medical care support teams consisting of specialized doctors stationed in respective prefectures was established to secure the stable recuperation of CJD and other patients, as well as a system of technical support for doctors treating CJD patients.

2) Support for patients and the bereaved

Counselling activities for the bereaved are conducted with the aim of relieving the mental distress of bereaved whose children, spouses, etc. was lost to HIV infection caused by blood products. In the meantime, support is being offered through support network activities, particularly through telephone counselling conducted by families whose patients was lost to CJD, with the aim of improving the welfare of patients and their families. Efforts are also being made to eliminate any prejudice and discrimination against the people that are infected with HIV and so on.

3) Condolence activities

As a measure of consoling the spirit of the sufferers, an "Oath Monument" was set up in the front garden of Ministry of Health, Labour and Welfare (August 1999), in declaring the

determination to do its best efforts to secure the safety and efficacy of drugs and to prevent any recurrence of miserable incidents like the HIV infections caused by drugs.