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Supreme Court of Japan

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2005 (A) 947

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Date of the judgment (decision)	2008.03.03
Case Number	2005 (A) 947

Reporter	Keishu Vol. 62, No. 3
Title	Decision concerning a case in which, with regard to a drug-induced incident wherein a patient, who was given unheated blood products contaminated with HIV (Human Immunodeficiency Virus), developed Acquired Immune Deficiency Syndrome () and died, the court found the person who held the post of the Director of the Biologics and Antibiotics Division of the Pharmaceutical Affairs Bureau of the Ministry of Health and Welfare at the time of the incident to be guilty of the crime of causing death through negligence in the pursuit of social activities
Case name	Case charged for causing death through negligence in the pursuit of social activities
Result	Decision of the Second Petty Bench, dismissed
Court of the Second Instance	Tokyo High Court, Judgment of March 25, 2005
Summary of the judgment (decision)	With regard to the drug-induced incident wherein a patient, who was given unheated blood products contaminated with HIV (Human Immunodeficiency Virus), developed AIDS (Acquired Immune Deficiency Syndrome) and died, given the circumstances where the unheated blood products, which were widely used at the time of the incident, contained a considerable amount of products contaminated with HIV, and it was foreseeable, as an almost inevitable result, that the use of these products would cause patients to get infected with HIV and develop AIDS, a disease without no effective remedy, and a large number of patients would die with high probability, not only a duty in pharmaceutical administration but also a duty of care under criminal law, which is required to be fulfilled in social life by a person engaged in the service for preventing drug-induced hazards, should be imposed on the person in charge of pharmaceutical

	administration with regard to the manufacture, use and safety of the products; since the accused, who held the position of the Director of the Biologics and Antibiotics Division of the Pharmaceutical Affairs Bureau of the Ministry of Health and Welfare, occupied a central position in the ministry in taking countermeasures against AIDS induced by said products, and also had a role in assisting the Minister of Health and Welfare to jointly execute pharmaceutical administration with the aim of preventing drug-induced hazards, the accused had the duty to take necessary and sufficient measures in pharmaceutical administration, including consulting with other bureaus and divisions of the ministry when necessary and encouraging the parties concerned to take actions as required; therefore, the accused, for neglecting to fulfill this duty by unthinkingly leaving the sale and use of the products as they were, should be found to be guilty of the crime of causing death through negligence in the pursuit of social activities.
References	First sentence of Article 211 of the Penal Code (prior to revision by Act No. 31 of 1991)
Main text of the judgment (decision)	The final appeal is dismissed.
Reasons	I. Determination on the reasons for final appeal The reasons for final appeal argued by the appeal counsels, JINGU Toshio, et al., including those alleging violation of the Constitution and violation of a judicial precedent, are in effect assertions of errors in fact-finding or unappealable violations of laws or regulations, and none of them can be regarded as a reason for final appeal permissible under Article 405 of the Code of Criminal Procedure. II. Determination by this court's own authority After considering the arguments, however, we decided to make a determination by this court's own authority with

regard to whether or not the accused can be deemed to have committed the crime of causing death through negligence in the pursuit of social activities.

1. Outline of the facts of the case

According to the judgment of prior instance and the findings of the judgment of first instance affirmed by the former, the outline of the facts of the case is as follows.

(1) Position of the accused

The accused, during the period from July 16, 1984 until June 29, 1986, held the post of the Director of the Biologics and Antibiotics Division of the Pharmaceutical Affairs Bureau of the Ministry of Health and Welfare, whose duty was to improve and promote public health, and supervised the overall affairs concerning the licensing of the manufacturing business and import/sales business of the biological products subject to the jurisdiction of said division, approval of manufacture and import, and examination and inspection of such products. During that period, the accused was in the position responsible for securing the safety of blood products and other biological products and preventing the occurrence of hazards to the public arising from the use of such products.

(2) Provisions of laws and regulations on pharmaceutical administration

The execution of the administrative affairs concerning pharmaceutical products, etc. by the Pharmaceutical Affairs Bureau of the Ministry of Health and Welfare was referred to as pharmaceutical administration and governed by the Pharmaceutical Affairs Act as a basic act. Based on the lessons learned from the experience of the drug-induced incidents such as the Thalidomide Case and the SMON Case, revision was made to said Act by way of the Act for Partial Revision to the Pharmaceutical Affairs Act (Act No. 56 of 1979; promulgated on October 1, 1979), for the purpose of preventing the occurrence of damage due to the use of pharmaceutical products. The Pharmaceutical Affairs

Act after said revision (the one effective when the accused held the post of the Director of the Biologics and Antibiotics Bureau; the same shall apply hereinafter) included provisions aimed at securing the quality, effectiveness and safety of pharmaceutical products. It vested the Minister of Health and Welfare with the power to issue an order of recall under Article 70 of said Act on condition of rescission of approval under Article 74-2, paragraph (1) of said Act, issue an emergency order under Article 69-2 of said Act, and take other measures.

(3) Hemophilia and therapeutic products for hemophilia

Hemophilia is a hereditary disease which exhibits uncontrolled bleeding due to congenital deficiency or low activity of specific human blood coagulation factors, Factor VIII or Factor IX. Hemophilia A is caused by congenital deficiency, etc. of Factor VIII, and Hemophilia B is caused by congenital deficiency, etc. of Factor IX. There is no radical therapy for hemophilia, and hemophiliac patients usually receive replacement therapy in which they are given a replacement substance of the blood coagulation factor that they lack. As therapeutic blood products, concentrated blood coagulation factor products were developed by extracting and refining Factor VIII or Factor IX taken from human blood, and concentrated blood coagulation Factor VIII products (hereinafter referred to as "Factor VIII products") and concentrated blood coagulation Factor IX products (hereinafter referred to as "Factor IX products") started to be used for Hemophilia A patients and Hemophilia B patients, respectively. In medical institutions in Japan, hemophiliac patients were given foreign unheated Factor VIII products and unheated Factor IX products, which were made of blood plasma in human blood taken in the United States and other foreign countries. These products were manufactured or imported with approval of the Minister of Health and Welfare. Unheated Factor IX products were said to have "efficacy or effect," which is one of the requirements for

approval, in treating "Factor IX deficiency," and thought to be applicable not only to congenital deficiency but also to acquired deficiency. In particular, unheated Factor IX products were widely given to patients with impaired liver function during surgery because these patients easily bled due to the decrease in blood coagulation factors produced by the liver.

(4) Death of the victim

Green Cross Corporation (hereinafter referred to as "Green Cross") manufactured and sold Christmassin, an unheated Factor IX product made of the mixture of blood plasma imported from the United States and blood plasma taken in Japan. During the period from January 13 to February 10, 1986, Green Cross sold a total of 160 bottles of Christmassin to a trading company which then sold a total of seven out of the 160 bottles to Osaka Medical College Hospital on March 27 and 29, 1986. A doctor of said hospital, during the period from April 1 to 3, 1986, at the hospital, gave three of the seven bottles (1,200 units in total) to a patient who underwent an operation for sclerosis of esophagus varices associated with impaired liver function (hereinafter referred to as the "victim"), thereby causing the victim to become infected with Human Immunodeficiency Virus (hereinafter referred to as "HIV") around that time. As a result, no later than September 1993, the victim developed an acid-fast bacteria infection and other symptoms of Acquired Immune Deficiency Syndrome (hereinafter referred to as "AIDS"), and died at said hospital in December 1995.

(5) Facts concerning the foreseeability and avoidability of the result

(a) Along with the ever-increasing number of AIDS patients, which had been defined in 1982 in the United States as a new disease with unfavorable prognosis, the number of cases of AIDS occurring in hemophiliac patients also increased. Through the subsequent progress in virological study on the true character of AIDS, it was found that AIDS was a

disease caused by blood-borne infection with HIV, and hemophiliac patients contracted AIDS because of the use of the conventional blood products, and this view was widely accepted in the medical profession. Also in Japan, it became known that the percentage of HIV carriers in hemophiliac patients had reached a significantly high level. On March 21, 1985, newspaper reports revealed that two AIDS carriers were found among hemophiliac patients at Teikyo University Hospital. The AIDS Study Council, managed by the Infectious Disease Control Division of the Health Service Bureau of the Ministry of Health and Welfare, recognized as AIDS patients three hemophilia patients (two of them were the aforementioned patients of Teikyo University Hospital) on May 30, 1985, and another two hemophilia patients on July 10, 1985. Four of these hemophilia patients had already passed away before being recognized as AIDS patients.

(b) The international research conference on AIDS, arranged jointly by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO), was held from April 15 to 17, 1985, in Atlanta, Georgia, the Untied States. From Japan, Doctor SHIOKAWA Yuichi, the president of the AIDS Study Council of the Ministry of Health and Welfare, Doctor KURIMURA Takashi, the chairperson of the Subcommittee on Diagnostic Criteria for AIDS, and Doctor KITAMURA Takashi, the chief of the Laboratory of Special Pathogens of the National Institute of Health, attended the conference. On April 19, immediately after the conference, the WHO recommended that when giving blood coagulation factor products to hemophilia patients, Member countries should use products treated by heating or other steps to kill viruses, and Doctor KITAMURA's report on the WHO recommendation was placed in the journal "Nihon Iji Shinpo," the June 8 issue. In November 1985, then Director of the Pharmaceutical Affairs Bureau of the Ministry of

Health and Welfare repeatedly manifested, when responding to the questions in the Diet, that he/she understood that "the examination of heated Factor IX products is also being conducted with all speed and priority, approval will be granted for these products by the end of the year, and then the safety of blood coagulation factor products to be used for hemophilia patients will be secured." At the eighth meeting of the Blood Product Investigation Board of the Special Committee on Blood Products of the Central Pharmaceutical Affairs Council, held on December 19, 1985, board members presented an opinion that "when heated products are approved, the Ministry of Health and Welfare should give instruction not to use unheated products," and as requested by the chair of the board, this opinion was recorded in the minutes of the meeting. Also at the fourth meeting of the Special Committee on Blood Products held on December 26, committee members presented an opinion to the same effect, which was arranged by the official in charge of the Ministry of Health and Welfare and recorded in the minutes of the meeting in the following form: "Among blood coagulation factor products, priority is given to heated products in the examination and approval procedures; the procedure for invalidating approval of unheated products should be conducted promptly, and instruction should be given to the companies that currently have approval only for unheated products, to develop heated products as quickly as possible." The minutes were displayed to the persons concerned, including the accused.

(c) In late March or early April of 1985, the accused, in the capacity of the Director of the Biologics and Antibiotics Division, announced a policy of granting approval as soon as possible for heated Factor VIII products, which had been reported as being effective in inactivating HIV and were subject to clinical testing at that time. According to this policy, in July 1985, approval was granted for heated Factor VIII products manufactured by five pharmaceutical

companies. In July, the accused, in the capacity of the Director of the Biologics and Antibiotics Division, announced a policy of also speeding up the grant of approval for heated Factor IX products. As a result, in December 1985, approval of import was granted for heated Factor IX products dealt with by Cutter Japan Ltd. (hereinafter referred to as "Cutter Japan") and Green Cross, and these companies started to sell the approved products no later than January 1986. In addition, among unheated Factor IX products available at that time, there were such products that were made only of blood plasma taken in Japan, which was said to be free from HIV, and those that were treated with ethanol, which was reported as being effective in inactivating HIV (heated Factor IX products, together with these two types of unheated Factor IX products, shall hereinafter be referred to as the "Heated Products, etc.," and other unheated Factor IX products shall hereinafter be referred to as the "Unheated Products"). Therefore, since the supply of heated Factor IX products started, the supply of the Heated Products, etc. came to meet the overall demands for replacements of Factor IX in Japan, and it was also possible for Cutter Japan and Green Cross to supply heated Factor IX products beyond the volume of their sales of unheated Factor IX products in the past. Furthermore, in addition to giving Factor IX products, there were other therapeutic methods by which the bleeding in patients with impaired liver function could be stopped.

2. The negligence of the accused found by the judgment of first instance and the judgment of prior instance
Under the circumstances described in 1(5)(a) and (b), the accused could have foreseen, around by the end of 1985, the risk that if he/she allowed the continued use of the Unheated Products in the medical institutions in Japan as before, this would cause HIV-free patients, if they were given such products, to become infected with HIV, and then develop AIDS and die. The accused actually recognized or could

have easily recognized the circumstances described in (c). Therefore, the accused, at the time when it became possible for Cutter Japan and Green Cross to supply heated Factor IX products, had the official duty of care to prevent HIV infection due to the use of the Unheated Products as well as the onset of AIDS and death arising therefrom to the greatest possible extent by taking measures, while making arrangements by him/herself or consulting with the relevant bureaus and divisions of the Ministry of Health and Welfare to request them to exercise their power, to [1] have the aforementioned two companies immediately discontinue selling unheated Factor IX products and recall already marketed but not yet used unheated Factor IX products as promptly as possible by replacing these products with their heated Factor IX products, and [2] have doctors who intended to use Factor IX products refrain from the non-urgent and non-essential use of the Unheated Products. However, the accused neglected to fulfill this duty by letting pharmaceutical companies handle the Unheated Products at their discretion and unthinkingly leaving the sale and use of the products as they were; through such negligence, the accused caused death to the victim as described in 1(4) above.

3. This court's determination

The counsels' arguments can be summarized as follows. [1] Administrative guidance is, by nature, a de facto measure to encourage voluntary actions, and no public officer is obliged to give administrative guidance. [2] For preventing the occurrence of drug-induced incidents, the primary responsibility rests with pharmaceutical companies that sell drugs and doctors who prescribe drugs, whereas the Ministry of Health and Welfare only has secondary or guardian-like responsibility, and therefore the ministry should exercise its power in compliance with the statutory requirements. In addition, in order to allege the criminal responsibility of an

individual public officer rather than the civil or tort liability of the State, the public officer must be found to have a high level of duty to act to the extent that he/she is allowed to exercise the legal power of supervision. However, this requirement is not met in the present case. [3] The power of supervision under the Pharmaceutical Affairs Act that should have been exercised in the present case does not fall under the jurisdiction of the Biologics and Antibiotics Division. Based on these arguments, the counsels contend that the accused does not have the duty to act for which he/she should be held to be responsible for negligence under criminal law.

It is true that administrative guidance per se is a de facto measure to encourage voluntary actions, and it is not a legal duty to give administrative guidance. It is also true that for preventing the occurrence of drug-induced incidents, the primary responsibility rests with pharmaceutical companies and doctors, whereas the State's power of supervision is based on secondary or guardian-like responsibility and such power should be exercised by taking various factors into consideration because it constitutes intervention by the public authority. In view of this, even though a public officer's inaction to take these measures may make the public officer responsible in relation to his/her duties or make the State liable for compensation, it does not go beyond that level to immediately make the public officer him/herself responsible under criminal law.

However, according to the facts mentioned above, we can find the following circumstances: [1] The Unheated Products, which were widely used at the time of the incident, contained a considerable amount of products contaminated with HIV, and although there remained medically unexplained mysteries, it was foreseeable, as an almost inevitable result, that the use of these products would actually cause the patients to become infected with HIV and develop AIDS, and since there was no effective remedy to

cure patients who developed AIDS, most patients would die with high probability. [2] It cannot necessarily be said that at the time of the incident, the risk of the Unheated Products was shared among the parties concerned, and it was impossible for doctors and patients to distinguish whether or not the Unheated Products that they were going to use were contaminated with HIV, which means that doctors and patients could hardly be expected to avoid the result of HIV infection. [3] In light of the risk of the Unheated Products, which had been approved by the State, the sale or use of the products should have been discontinued, or at least, the use of the products should have been avoided except when it was inevitably necessary for medial purposes; if the State, despite such situation, failed to indicate a clear policy, it was likely that the Unheated Products would be continued to be sold or used casually or by taking advantage of the lack of the State's policy, and in view of what had happened previously, there was a concrete risk that such likelihood would become reality if the handling of the products was left in the hands of pharmaceutical companies, etc.

Under these circumstances, we can find that there was a serious risk that should be the reason for allowing the Minister of Health and Welfare to exercise the power of supervision to take various compulsory measures as vested under the Pharmaceutical Affairs Act, such as issuing an emergency order under Article 69-2 of said Act, for the purpose of preventing the occurrence of drug-induced hazards. Under such circumstances, we can not only say that a specific duty in pharmaceutical administration to take necessary and sufficient measures to prevent such hazards came to exist, but we should also say that a duty of care under criminal law, which is required to be fulfilled in social life by a person engaged in the service for preventing drug-induced hazards, should be imposed upon the person in charge of pharmaceutical administration with regard to the manufacture, use and safety of the Unheated Products.

Preventive measures required under the aforementioned circumstances include not only compulsory supervisory measures provided in law; if it can be reasonability expected that the purpose of prevention of hazards can be achieved by taking other measures such as encouraging voluntary actions, such measures can also be regarded as preventive measures, irrespective of whether or not we call them administrative guidance. In the present case, such measures are supposed to be taken against pharmaceutical companies, etc. that are subject to the power of supervision of the Minister of Health and Welfare, and they can also be deemed as reasonable preventive measures.
The Unheated Products allegedly related to AIDS fell under the scope of blood products that were subject to the jurisdiction of the Biologics and Antibiotics Division where the accused served as director. Therefore, the accused occupied a central position in the Ministry of Health and Welfare in taking countermeasures against AIDS induced by these products, and also had a role in assisting the Minister of Health and Welfare and jointly executing pharmaceutical administration with the aim of preventing drug-induced hazards. In this respect, it is obvious that the accused had the duty to take necessary and sufficient measures in pharmaceutical administration, including consulting with other bureaus and divisions of the ministry when necessary and encouraging the parties concerned to take actions as required. Furthermore, we cannot find any serious legal or factual obstacles that made it impossible or difficult for the accused to take the measures suggested by the court of second instance. Therefore, although the responsibility for the victim's death should not be imposed exclusively on the accused, the accused cannot evade responsibility for it.
We can affirm as justifiable the holdings of the court of second instance that are in line with our reasoning.

Therefore, according to Article 414 and Article 386,

	paragraph (1), item (iii) of the Code of Criminal Procedure, the decision has been rendered in the form of the main text by the unanimous consent of the Justices.
Presiding Judge	Justice FURUTA Yuki Justice TSUNO Osamu Justice IMAI Isao Justice NAKAGAWA Ryoji

(This translation is provisional and subject to revision.)