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THE HIV LITIGATION AND ITS SETTLEMENT [IN JAPAN][1]

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Abstract: As early as 1983, Japan's Health and Welfare Ministry had reason to know that the use of unheated blood products by hemophiliacs was infecting them with HIV, the AIDS virus. Although heated—and safe—blood products were already available from the United States, government approval in Japan was deliberately delayed for almost three years while local pharmaceutical companies developed the products. By the time the unheated blood products were all withdrawn from the market, many of Japan's hemophiliacs had contracted HIV. A number of them, or their survivors, sued the government and the pharmaceutical companies. At the end of the consolidated trials, but before handing down their opinions, the two District Courts handling the cases made proposals for settlement that were accepted by the parties. The courts' reasons for recommending settlement were that time was of the essence in order to get relief to those still suffering and that remedies unavailable via the courts were possible through settlement.

I. INTRODUCTION

(1) As is widely known, a truly tragic incident occurred in Japan when unheated concentrated blood products containing the human immunodeficiency virus (HIV)[4] were imported from the United States and administered by transfusion to hemophiliacs.[5] This was termed the HIV-, or

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[1] Translated from Awaji Takehisa, *HIV soshô to wakai*, 1093 JURISUTO 52 (1996). Notes, unless otherwise indicated, are parenthetical or other information contained in the original text. Cites in the original converted to Pacific Rim Law & Policy Journal style where possible.

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[4] It is also known as the AIDS virus.

[5] This is the so-called third route of HIV transmission. In addition, it has turned out that there is a fourth route, that is, where contaminated blood products are administered to patients other than hemophiliacs, such as those with liver disease. [Translator's note: According to the Japanese media's terminology, the first two routes of HIV transmission are through sexual contact and prenatal infection. *See, e.g.*, Yamamuro Hiroyuki, *Officials Must Account for Their Actions*, DAILY YOMIURI, Oct. 30, 1996, at 6.]

AIDS-contaminated blood products incident. Of Japan's approximately 5,000 hemophiliacs, about forty percent or between 1,800 and 2,000 people are said to be infected with HIV. One-third of them have already experienced AIDS symptoms. Of these, two-thirds are already dead. The HIV-, or AIDS-contaminated blood products litigation, began when some of these victims filed suit against the five pharmaceutical firms that had produced and sold the [contaminated] blood products,[6] and against the Japanese government, which is responsible for regulating pharmaceuticals.[7] From the companies, the plaintiffs sought compensation in contract for breach of the duty to give careful consideration to the safety of their products, and in tort under the Civil Code.[8] From the government, the plaintiffs sought to recover damages on the basis of negligence.[9]

The HIV litigation started in 1989. The first lawsuit was filed in May of that year, at Civil Section No. 18, Osaka District Court. The first lawsuit in Tokyo was filed in October at Civil Section No. 15, Tokyo District Court. This came about through the devoted efforts of attorneys and supporters who helped the hemophiliacs with HIV at a time when it was extremely difficult to do so because of prejudice and discrimination against people with AIDS. Subsequently, as the facts were brought to light in court and the legal issues were clarified, the plaintiffs gradually gained the support of public opinion, partly due to reports in the news media.[10] Under these circumstances, the consolidated trial in Tokyo[11] ended in March 1995, and the consolidated trial in Osaka,[12] in July. On October 6, 1995, while the

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[6] They are Green Cross Corp., Baxter International Inc., Nippon Zōki Pharmaceutical Co., Bayer Pharmaceutical Ltd., and Chemo-Sero-Therapeutic Research Institute.

[7] The ministry in charge of this matter is the Health and Welfare Ministry.

[8] MINPŌ § 709.

[9] Kokka baishōhō [National Compensation Act], Law No. 125 of 1947, § 1(1). In addition to this civil litigation, criminal complaints have been filed with prosecutors against the medical personnel, executives of pharmaceutical firms, and bureaucrats who were involved in this matter. It is possible that the HIV criminal litigation will soon start. [Translator's note: Between September and October 1996, prosecutors indicted Abe Takeshi, *infra* note 25, three former presidents of Green Cross Corp., and Matsumura Akihito, former director of the Biologics and Antibiotics Division (*seibutsu seizai kachō*) of the Health and Welfare Ministry, for professional negligence resulting in death, a criminal offense punishable by up to five years in jail. *See 3 Former Presidents of Green Cross Indicted,* DAILY YOMIURI, Oct. 10, 1996, at 2; DAILY YOMIURI, *supra* note 5, at 6. Prosecutors claim that Matsumura failed to instruct doctors to stop using unheated blood products while he was director from July 1984 to June 1986, although he was aware of their potential to transmit HIV. *See Matsumura Indictment Expected in Unheated Blood Product Scandal,* DAILY YOMIURI, Oct. 24, 1996, at 2. Prosecutors decided not to seek criminal charges against Gunji Atsuaki, *infra* note 24, Matsumura's predecessor at the Division. *Id.*]

[10] The NHK [national public television] report was particularly outstanding.

[11] Four suits had been filed at the Tokyo District Court.

[12] Ten suits had been filed at the Osaka District Court.

parties were awaiting decision, each court made an initial proposal for out-of-court settlement and issued a "Statement of Opinion on the Recommended Settlement." On March 7, 1996, the courts presented their second proposals, suggesting ways to resolve matters not mentioned in the first proposals. On March 29, 1996, the parties accepted the courts' proposals.

(2) Part II of this article outlines the development of the HIV litigation in Japan. Part III introduces the contents of the court proposals and Statements of Opinion and analyzes their legal significance. Part IV concludes the article with an examination of the contents of the final settlement and an assessment of this settlement as a whole.

There have been several valuable documents written by journalists regarding the course of the HIV litigation.[13] At the present stage, however, since the facts ("the truth") are still under investigation, led by the Diet and by the media, and since the courts did not make the findings of fact that would accompany a court opinion,[14] there are a number of points that it is difficult to describe clearly. I hope that the determination of the facts will be advanced hereafter by the efforts of the persons concerned. In this article, I will state the facts only to the extent necessary to legal evaluation.[15]

II. THE DEVELOPMENT OF THE [HIV] INCIDENT

(1) I will begin by reviewing how this all happened. Then, I will describe how the danger from the unheated blood products was discovered, with special emphasis on the situation in the United States at that time, and give a sketch of the measures taken—and not taken—in Japan under the

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[13] *See* YOMIURI SHIMBUN, May 19, 1996, at 12 (containing a bibliography on these AIDS cases). *See also* SAKURAI YOSHIKO, AIDS HANZAI: KETSUYŪBYŌ KANJA NO HIGEKI [THE AIDS CRIME: THE TRAGEDY OF HEMOPHILIACS] (1994) and HIROKAWA RYŪICHI, YAKUGAI AIDS NO SHINSŌ [THE TRUTH OF THE AIDS-CONTAMINATED BLOOD PRODUCTS INCIDENT] (1996) (both books particularly important for learning the facts of the AIDS-contaminated blood products incident). [Note 1 in the original article.]

[14] This was because the lawsuits ended in settlement.

[15] In addition to SAKURAI, *supra* note [13], and HIROKAWA, *supra* note [13], I also rely on Sugiyama Shinichi, *HIV soshō: wakai to sono go no tenbō,* 498 HŌGAKU SEMINAR 4 (1996), the plaintiffs' trial briefs, the defendant government's trial briefs, the defendant pharmaceutical firms' trial briefs, and articles that appeared in ASAHI SHIMBUN, YOMIURI SHIMBUN, and MAINICHI SHIMBUN. For the sake of simplicity, I will generally not cite statements concerning facts generally accepted in light of several written materials and press reports. I will, however, quote parts that I think particularly essential to the discussion. [Note 2 in the original article.]

circumstances. This should furnish the factual basis for making a judgment concerning whether the defendant pharmaceutical firms and the government were negligent or not.

(2) Hemophilia is a disease characterized by a congenital lack of a coagulation factor[16] in blood plasma and a consequent difficulty in stopping bleeding. The disease is carried by sex-linked inheritance, and its symptoms appear in males. In the past, the only treatment[17] for hemophilia was to transfuse whole blood, just as it was taken from donors, or to transfuse blood plasma. But following the authorization in 1967 of Blood Product I, created by the Cohn [ethanol] fractionation technique, cryoprecipitate ("cryo"), which is made by extracting Factor VIII from plasma in fresh blood,[18] was approved in 1970 under the Pharmaceutical Affairs Act[19] for purposes of treating type A hemophiliacs, and was put in use.[20] Ordinarily, cryo is made from one or two donors' blood.

Subsequently, pharmaceutical firms started producing blood products that densely concentrated these blood-clotting factors.[21] They were approved by the Japanese government in 1972 as to Factor IX and in 1978 as to Factor VIII. Because concentrated blood products were relatively easy to use, and because the pharmaceutical companies actively promoted their sale, it became common for hemophiliacs to self-inject them at home. Further, in February 1983, the government allowed coverage under the national health insurance of such home treatment. As a result, concentrated blood products came to be used in large quantities.

However, these blood products were made from blood collected from paid [donors] in the United States. In the manufacturing process, an immense quantity of blood plasma, from as many as 2,000 to 25,000 donors,[22] was pooled in one container. Because there were individuals infected with HIV among these numerous donors, the entire pool of plasma would become contaminated with HIV. And because these contaminated blood products were imported from the United States and used by many

[16] Type A hemophiliacs lack a substance known as Factor VIII, whereas type B hemophiliacs lack Factor IX.

[17] At present, it is impossible to cure hemophilia.

[18] Cryo is made by freezing or freeze-drying the precipitate produced when blood plasma is frozen, then slowly melted down.

[19] Yakujihō [Pharmaceutical Affairs Act], Law No. 145 of 1960.

[20] Cryo does not contain Factor IX.

[21] These products were not heat treated.

[22] Among them were a number of drug addicts and homosexual men.

hemophiliacs, it led to the disaster of as many as forty percent of Japanese hemophiliacs' contracting HIV.

(3) Between June and August of 1981, the American Centers for Disease Control (CDC) reported that *Pneumocystis carinii* pneumonia and Kaposi's sarcoma, both of which had been extremely rare in the United States, were prevalent among homosexual men, and issued an epidemiological opinion suggesting that immune deficiency related to some unknown factor common to these patients might be the common underlying medical condition for these diseases. In July 1982, the CDC reported in the *Morbidity and Mortality Weekly Report (MMWR)* that three hemophiliacs, who had been using unheated concentrated blood products, developed *Pneumocystis carinii* pneumonia, and that two of them suffered from cellular immune deficiency. The report explained that, although the cause of this immune deficiency was not clear, the circumstances suggested that they had become infected through the use of blood products. This was the first time that AIDS cases were reported. In December of that year, the *MMWR* reported four more cases and one suspected case of AIDS in hemophiliacs, with the comment that the number of such cases was increasing and that AIDS might put hemophiliacs in serious peril.

In March 1983, the CDC warned in the *MMWR* that it appeared that hemophiliacs were contracting AIDS from blood or blood products, and made several recommendations along with other agencies. Among them were recommendations to avoid blood donations from members of high-risk groups, and to conduct research to develop safer products for hemophiliacs. In the same month, Travenol Ltd.,[23] which had developed a heat treatment method to cope with the threat of hepatitis transmission, was licensed to start manufacturing heated blood products. In May of that year, the Food and Drug Administration (FDA) recommended this to other pharmaceutical firms, based on the determination that it would similarly prevent HIV transmission. In June [1983], Travenol informed the director of the Biologics and Antibiotics Division ["B.A.D."] of Japan's Health and Welfare Ministry[24] that it had voluntarily recalled certain of its products from the American market, because one of its donors had shown symptoms indicating AIDS shortly after donating blood used for plasma. At that time,

[23] Now Baxter International Inc.

[24] The report from Travenol went to Gunji Atsuaki, then director of the Biologics and Antibiotics Division. The Division was in charge of matters related to blood and blood products at that time.

other products made from this same blood plasma [pool] had already been imported into Japan. Because they had not yet been supplied to the market, steps were taken to ban shipment.

(4) In Japan, immediately after the director of B.A.D. received the Travenol report that it had recalled blood products, an AIDS research team was organized within the Health and Welfare Ministry.[25] It is said that the B.A.D. director did not inform the research team that Travenol had pulled [certain of] its blood products off the market.

In July 1983, after a hemophiliac developed AIDS symptoms and died at the Teikyō University Hospital,[26] there was a discussion at the research team's second meeting on whether they should recognize this as a case of AIDS, but they decided not to do so after all.[27] Subsequently, in May 1985, two months after the first Japanese case of AIDS was officially announced,[28] the research team officially recognized that the hemophiliac [in the 1983 case] had died of AIDS. While the circumstances surrounding the diagnosis of the first officially-recognized AIDS patient are currently in controversy,[29] people wonder why the research team only belatedly acknowledged the hemophiliac at the Teikyō University Hospital as an AIDS patient, and suspect that they tried to conceal the existence of AIDS. Criticism behind this suspicion is that, if they had recognized the hemophiliac as the first AIDS patient in July 1983, Japan would have started taking countermeasures to cope with AIDS from that point, and heated blood products for hemophiliacs would have been considered in a totally different light.[30]

Is it not true that the B.A.D. director proposed at the AIDS research team's meeting in July 1983 that heated blood products be imported on an emergency basis from the United States? Why did he suddenly change his position in a week? As to these points, huge doubts remain. In an internal document which was "discovered" at the Health and Welfare Ministry in January 1996, there are written descriptions of the B.A.D. director's perception of the danger of, and his ideas of how to cope with, HIV

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[25] The head of this research team was Abe Takeshi, former vice president of Teikyō University.

[26] [Team leader] Abe was the doctor in charge.

[27] Shortly thereafter, an American AIDS specialist came to Japan and determined that this patient had died of AIDS. Nevertheless, the research team did not rectify its conclusion at that time.

[28] The patient was a homosexual man living in the United States who had returned to Japan for a short visit.

[29] It is doubted that he had yet developed AIDS symptoms. YOMIURI SHIMBUN, May 26, 1996.

[30] As a consequence, HIV transmission to hemophiliacs could likely have been minimized.

transmission through unheated blood products as of July 1983. According to a document dated July 4, 1983, measures to be taken were as follows:

(i) The ministry will order the AIDS research team to recommend the use of heated blood products.

(ii) The ministry will direct Travenol Ltd., an American corporation, to file an application at once for urgent approval of its heated blood products in Japan.

(iii) The ministry will direct businesses by means of administrative guidance not to handle unheated blood products made from blood collected in the United States.

He reached a different conclusion in a document of July 11, however, stating that emergency imports of heated blood products through extralegal measures were undesirable, and that the ministry would not put a total ban on unheated blood products from the United States. People suspect that something must have happened during this [one-week] period. In the AIDS Survey Report released by a Health and Welfare Ministry survey team on March 19, 1996, this director, in response to interrogation, answered that, in his recollection, he had never considered emergency imports [of heated blood products], that the document [of July 4, 1983,] was a discussion draft created only to form a basis for the investigation, but that it did reflect the Biologics and Antibiotics Division's atmosphere at the time quite well. Opinions of the members of the research team at the time are divided on the issue of whether there was a proposal for emergency imports.[31] While the facts are somewhat ambiguous, it can be inferred that the Biologics and Antibiotics Division already knew, with considerable certainty, the risk of HIV transmission from that period. As for imports of heated blood products at an early stage, it is reported that, although an official at B.A.D. again made such a proposal at the research team's fourth meeting in October 1983, Abe Takeshi, the head of the research team, furiously objected.[32]

At the research team's third meeting in August 1983, there was a discussion of switching [from unheated blood products] to cryo, and

[31] ASAHI SHIMBUN, Mar. 20, 1996.
[32] YOMIURI SHIMBUN, Feb. 26, 1996.

conflicting opinions were expressed.[33] In order to examine this issue, a subcommittee on blood products was set up under the research team.[34] Switching to cryo, like emergency imports of heated blood products, would have been a way to prevent HIV transmission to hemophiliacs. The subcommittee, however, at its first meeting in September 1983, decided not to switch to cryo and submitted a report to that effect in March 1984. The AIDS research team authorized the continued use of unheated blood products until clinical tests on heated blood products were fully performed. It is suspected that Abe was influential in leading the research team to such a conclusion, and that he considered the interests of a domestic pharmaceutical firm with which he had a connection. Thereafter, the use of unheated blood products mushroomed, partly because home use had been brought within the coverage of national health insurance and partly because the companies vigorously sought to increase sales by discounting the price.

In September 1984, it was discovered that twenty-three of Abe's patients were HIV-positive. Abe had sent blood samples of forty-eight of his patients to the United States for HIV testing. This fact was not made public, however, and the number of hemophiliacs with HIV quietly grew with the use of unheated blood products.

(5) As mentioned above, in March 1985, a homosexual man was officially recognized as the first AIDS patient in Japan, and the case of the hemophiliac who had died at the Teikyō University Hospital was subsequently recognized in May of that year. Prior to this, clinical tests of heated blood products had been conducted since February 1984.[35] By May 1985, the domestic firms[36] had developed the heat treatment technology,[37] so applications for approval of heated blood products were filed,[38] and the approvals were given for Factor VIII in July of that year. The government licensed the products of the foreign and domestic firms at exactly the same time. This was two years and four months later than the United States' action in this matter. In December 1985, heated blood products for Factor IX were also licensed.

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[33] It is reported that Abe vehemently opposed this proposal. YOMIURI SHIMBUN, Feb. 26, 1996.

[34] Kazama Mutsumi, then Associate Professor, Teikyō University, a former student of Abe, headed the unit. Of eleven members of this subcommittee, eight were hemophilia specialists. There was no, or at least there were very few, specialists in hematology or virology. *See* SAKURAI, *supra* note [13], at 40.

[35] Abe performed the tests as supervising doctor for the five pharmaceutical firms involved.

[36] Green Cross was the largest.

[37] It is said that the domestic firms were later in developing this technology than the foreign firms.

[38] Foreign firms filed their applications in April 1985; Green Cross, at the end of May.

Pharmaceutical firms, however, did not recall [already distributed] unheated blood products promptly. Nor did the Health and Welfare Ministry direct them to do so. Consequently, even after heated blood products were introduced to the market, unheated blood products already shipped were put to use and new shipments of unheated blood products were made.[39] With this, the disaster spread.

(6) As stated above, following these events, the HIV litigation was commenced in 1989, the trials ended in 1995, and the courts presented their proposals for settlement in October 1995 and in March 1996. I will now turn to the contents of the court proposals and examine their legal significance.

III. THE [COURTS'] RECOMMENDATIONS AND PROPOSALS FOR SETTLEMENT, AND THE LIABILITY OF THE CORPORATIONS AND THE GOVERNMENT

A. The Courts' First Proposals for Settlement, "Statements of Opinion," And Their Legal Significance

(1) On October 6, 1995, the Tokyo and Osaka District Courts each presented to the parties proposals for out-of-court settlement and "Statements of Opinion on the Recommended Settlements" ("Statements of Opinion"). The proposals were identical, and the contents of the "Statements of Opinion," too, were about the same in principle.[40]

In summary, the proposals were as follows:

(a) (i) The defendants shall jointly and severally pay ¥45,000,000 [approximately $360,000] per person as a lump sum settlement to compensate for the injuries of those infected with HIV[41] to all claimants alike, including the plaintiffs in this case.

(ii) The defendant pharmaceutical firms shall pay sixty percent of the

[39] It is reported that it took Green Cross two years and nine months after the approval of heated blood products in July 1985 to finish recalling all its unheated blood products. ASAHI SHIMBUN, Mar. 1, 1996, (Evening ed.).

[40] The statements of opinion differ in their level of detail.

[41] Those who have already developed AIDS and those who have died of AIDS are included.

settlement amount, and the government shall pay forty percent.

(iii) Of the amounts that the plaintiffs have received prior to this settlement from the [Friendship and Welfare] Foundation, fifty percent of the total of the special allowances, the bereavement gifts, and the bereavement lump sums, shall be subtracted from the amounts they are to receive under this settlement.

(iv) This settlement applies to those who have filed suit, but those who have yet to prove that they became infected with HIV through the use of unheated blood products shall be subject to this settlement upon producing such proof.

(v) The parties shall continue negotiations with respect to the treatment [of the victims] who have not yet filed suit.

(vi) The parties shall also continue negotiations with respect to the defrayal of litigation costs, including attorneys' fees and so forth.

(b) The parties shall also continue negotiations with respect to the so-called permanent measures expected to complement the lump sum settlement stated in (a) (i).

(2) Next, I will look into the "Statement of Opinion" issued by the Tokyo District Court with its proposal for settlement. In brief, its contents were as follows:

(a) To begin with, the court stated that, in light of the extraordinary nature of these cases, it was highly desirable that, for the benefit of both parties and particularly for purposes of providing immediate relief to the HIV-infected plaintiffs, the parties resolve their dispute through settlement, in a speedy and comprehensive manner.

(b) Then, the court pointed out four distinctive characteristics of these cases:

(i) The plaintiffs became infected with HIV through the continuous use of unheated concentrated blood products,

"pursuant to their doctors' advice and sincerely believing the products to be an effective medical treatment." Yet the majority of the plaintiffs had the misfortune to develop serious AIDS symptoms; further, due to the delay in notification of HIV infection, secondary infection took place as well.

(ii) Individuals with AIDS develop opportunistic infections, malignant tumors, and so forth, and ultimately die. Also, the reality is that they are subject to discrimination from society.

(iii) The number of Japanese hemophiliacs infected with HIV through concentrated blood products is said to be about 1,800 to 2,000. Over the past ten or so years following the first confirmed case of AIDS, the number of those suffering from AIDS has increased every year.

(iv) "This court believes that it is totally inexcusable from a social as well as a humanitarian perspective that the plaintiffs, born hemophiliacs through no fault of their own in the first place, have had to experience this fatal and excruciating disease, the agony of which can only be described as heartbreaking, just because they, in accordance with their physicians' advice, and sincerely believing the products to be an effective treatment, used unheated concentrated blood products accidentally contaminated with HIV."

(c) Furthermore, the court discussed the defendants' responsibility as follows:

(i) Manufacturers and dealers in pharmaceutical products have a duty to supply consumers with safe products. The Pharmaceutical Affairs Act provides that one may not sell, or manufacture or import with the intent to sell, pharmaceutical products contaminated with, or possibly contaminated with, pathogenic microorganisms.[42]

(ii) While the Health and Welfare Minister had an official duty

[42] Yakujihō, § 56(6).

to assure the safety of pharmaceutical products even under the prior Pharmaceutical Affairs Act, this duty has been fortified by new legislation. The amended Pharmaceutical Affairs Act clearly states that one of its purposes is to "ensure the safety of pharmaceutical products,"[43] and that, when authorizing the manufacture of a pharmaceutical product, the Health and Welfare Ministry should review its "side effects."[44] Moreover, in order to prevent harm to the public health due to [defective] pharmaceutical products from occurring or spreading, the procedure for emergency orders has been newly established.[45] It follows that the safety of pharmaceutical products is now one of the subjects that the Health and Welfare Minister should give utmost consideration in monitoring pharmaceutical affairs. Thus, the Health and Welfare Minister has a responsibility to exercise his or her powers to the maximum to ensure the safety of pharmaceutical products, taking steps to make sure that no products become contaminated with pathogenic microorganisms, and that no products contaminated with pathogenic microorganisms are manufactured or sold in Japan.[46] [The Minister must] protect the lives and health of the people from the side effects of pharmaceutical products and from defective pharmaceutical products.

(iii) Because the blood products that the defendant firms were manufacturing and selling were made by refining pooled blood plasma containing a great number of people's blood, and because the main raw material for the products was blood purchased in the United States, it was pointed out [from the beginning] that impurities such as viruses could be introduced in the process. As a matter of fact, many of those who were administered the defendant firms' products actually became infected with hepatitis, apparently because of the hepatitis virus in the products. On the other hand, it was made clear by the [U.S.] Public Health Service (PHS) and the Centers for Disease Control (CDC) that, since around July 1982, a syndrome later

[43] Yakujihō, § 1 [as amended by Law No. 56 of 1979].
[44] Yakujihō, § 14(2).
[45] Yakujihō, § 69-2.
[46] Yakujihō, § 56(6).

referred to as AIDS had appeared in type A hemophiliacs in the United States. Thereafter, as the number of such cases increased, it was determined that it was likely that a virus, transmitted through blood or blood products, was causing the disease; further, it was hypothesized that there were many people infected with the virus who had not yet developed the symptoms. Also, it was apparent that AIDS was a disease with a high mortality rate. Since early in 1983, the United States government issued numerous recommendations about measures to protect hemophiliacs from AIDS, among which was a suggestion to reject blood donors belonging to high-risk groups.

[The court] finds that the director of the Biologics and Antibiotics Division at the Health and Welfare Ministry knew the foregoing situation in the United States, for he had started collecting information on AIDS and hemophilia around the beginning of 1983. In addition, [he knew] from Baxter's report that, in June or July of that year, the company had voluntarily recalled products containing blood plasma from a donor suspected of suffering from AIDS. By then, the director had a strong suspicion that the cause of AIDS was a virus transmitted through blood or blood products. The AIDS research team at the Health and Welfare Ministry, too, was discussing the matter on the assumption that it was likely that AIDS was an infectious disease caused by a virus. There is some evidence of a proposal made by the director at the research team's second meeting in July 1983 that [heated blood products] be immediately imported. Moreover, around August of that year, when the CDC specialist diagnosed the Teikyō University Hospital case as AIDS, it became clear that there had been a hemophiliac suffering from AIDS in Japan. As a purely scientific matter, the cause of AIDS had not been established at that time and the AIDS virus had yet to be identified. However, considering the results of the studies conducted by the governmental agencies of the United States and the professional opinions based on those results, the fact that AIDS was brought on by a virus transmitted through blood or blood

products was, at least with regard to AIDS in hemophiliacs, becoming common knowledge among scientists.

(iv) The defendant pharmaceutical firms, "even under such circumstances, continued to sell their unheated blood products until they were licensed to manufacture and actually started the sale of heated blood products. Even after they had begun to sell heated blood products, they did not completely recall all unheated products, so some hospitals administered the unheated blood products [to patients] as before."

Under these circumstances, it must be said that the Health and Welfare Minister "should have known that hemophiliacs in Japan were exposed to the risk of contracting AIDS due to a virus transmitted through blood products. Furthermore, since it had been demonstrated that, once an individual developed AIDS, the mortality rate was extremely high, it was desirable that the Minister would take steps to prevent HIV transmission to hemophiliacs in Japan, such as giving ample information concerning the risk to the relevant agencies, institutions, and to hemophiliacs themselves, taking emergency measures to secure alternative blood products by enhancing the domestic supply of concentrated blood products or cryo made from blood donated in Japan, or by directing imports of, or accelerating the approval of, heated blood products, and, by exercising the power to issue emergency orders, as mentioned above, suspending the sale of unheated blood products made from blood plasma collected in the United States." However, Health and Welfare officials "did not take any of these meaningful measures, and it is difficult to deny that this delay in taking action resulted in the spread of a tragic injury, HIV transmission to hemophiliacs in Japan."

(v) Such being the case, [the court] believes that the defendant pharmaceutical firms should be primarily responsible for making reparation for losses described in (b), but that the defendant government, together with the pharmaceutical firms, should also be responsibile for urgently compensating plaintiffs for the terrible injuries caused by [HIV] transmission.

(d) Finally, the court emphasized the necessity by all means of resolving the dispute as soon as possible through settlement, stating that it was essential that those infected with HIV, including the plaintiffs, be quickly and comprehensively compensated for their losses through a settlement that uniformly and impartially remedied the situation of all these HIV victims.

(3) How should we evaluate the courts' first proposals for settlement and "Statements of Opinion" just described? The lawsuits actually terminated in settlement without judgments, as the courts had suggested. Accordingly, as an official matter, there are no judicial decrees demonstrating how the courts determined the liability of the corporations and the government. Even if this was the only way to work things out in these particular cases,[47] it is necessary in such serious cases that we clarify the defendants' legal responsibility both for the benefit of the victims, who suffered grave losses, and to make sure that such events will never be repeated.

As a matter of fact, if we read between the lines, it seems reasonable to suppose that the courts' determination of the defendants' liability was made clear in the "Statements of Opinion" regarding the recommended settlement.[48]

First, since passages concerning the defendants' responsibility in the "Statements of Opinion" were structured in a way that is used by the courts in officially determining legal responsibility, they could be easily converted into a judicial decree if they were put into a proper format and elaborated.[49]

Secondly, although the pharmaceutical firms' legal responsibility was discussed only in rather terse fashion in the "Statements of Opinion" probably because it was so obvious [that they were liable for the plaintiffs' losses], their legal duty, a prerequisite for holding them liable, was specified in (c) (i);[50] foreseeability, which is one of the elements of negligence,[51] was

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[47] In light of the existence of so many victims and the severe nature of the injuries, it seems fair to say that resolving the dispute through out-of-court settlement was the only realistic solution.

[48] *See* Iizuka Tomoyuki & Ito Toshikatsu, *HIV soshô: wakai kankoku wo dô miruka,* [492] HŌGAKU SEMINAR 17 (1995). [Note 3 in the original article.]

[49] Of course, it would be necessary that phrases like "has a responsibility to" (*sekimu ga aru)* be replaced with [more formal language] like "has a duty to" (*gimu ga aru*).

[50] The courts cite Yakujihō § 56(6), but in any case, it goes without saying that there is a duty of care for the safety of others under ordinary tort law. [MINPŌ § 709.]

set forth in (c) (iii); and the failure of their duty to avoid the [injurious] consequence was mentioned in the section concerning the pharmaceutical firms in (c) (iv).

It has been shown frequently in prior court opinions that pharmaceutical firms owe a heightened duty of care. Yet here, in my opinion, such a theory would have been unnecessary, for it seems to me that, with respect to the pharmaceutical firms in this case, intentional torts,[52] or at least gross negligence, could have been established. For example, Green Cross's U.S. subsidiary[53] had been sending information on the risk of unheated blood products to Green Cross since around the end of 1982.[54] Nevertheless, Green Cross kept on selling unheated blood products and did not recall them until over two years after the approval of heated blood products. It is entirely possible to call this gross negligence.

Thirdly, in regard to the government's responsibility, the "Statements of Opinion" specifically set forth, in (c) (ii), the purpose of the amended Pharmaceutical Affairs Act[55] and the Health and Welfare Ministry's regulatory powers which ought to have been applied in this case,[56] and explicated the contents of the government's legal duty. Then, in (c) (iii), [the Statements] pointed out the facts evidencing foreseeability. In addition, they listed, in the part of (c) (iv) concerning the government, the steps [the government] should have taken to avoid the [injurious] consequence.

If we look back upon the development of the incident described here, we may say that [the risk of harm] was foreseeable to the government early in 1983, at the latest, and that thereafter measures to avoid the [injurious] consequence should have been taken. Available measures ranged from the moderate step of providing information on the risk[57] to suspending the sale

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[51] MINPŌ § 709, or alternatively, breach of the duty to give careful consideration to the safety [of a product].

[52] Under the theory that acquiescence [to the injurious consequence] is an element of an intentional tort, an intentional tort is established when acquiescence [in addition to the fact that the actor knew the risk of harm and nevertheless proceeded to act] is shown. Some scholars, on the other hand, argue that it is sufficient that an actor knew the risk of harm and nevertheless proceeded to act, and that acquiescence is not a requisite element. According to them, an intentional tort can be established even if the plaintiff fails to prove the defendant's acquiescence.

[53] The Alpha Therapeutic Corporation.

[54] YOMIURI SHIMBUN, Mar. 4, 1996, (Morning and Evening eds.).

[55] Yakujihō § 1.

[56] Yakujihō §§ 14(2), 56(6), 69-2, etc.

[57] It is obvious that, had the information concerning the risk of HIV transmission been given to hemophiliacs, they would not have used such risky products, even considering their efficacy as a treatment for hemophilia.

of unheated blood products,[58] for which the ministry's regulatory power is a prerequisite. Further, it was possible to supply hemophiliacs with the substitutes for unheated blood products that they should have been provided, by switching to cryo or by importing heated blood products from the United States immediately. So the injuries were avoidable. It is this aspect that the "Statements of Opinion" pointed out, and it seems proper as a legal judgment as well.

Some take the phrase "transcending the dispute over the existence of legal responsibility," in the section entitled "The Proposal for Resolution through Settlement," as a basis for arguing that the "Statements of Opinion" do not presuppose the defendants' legal responsibility. It should be noted, however, that the courts did not say, "transcending legal responsibility." By definition, parties can come to a settlement only by abandoning a dispute between them. So considering the nature of the "Statements of Opinion," which recommended that the parties settle, it was instead natural that the courts used the phrase "transcending the dispute over the existence of legal responsiblity."

B. The Courts' Second Proposals for Settlement and "Statements of Opinion"

(1) On March 7, 1996, the Tokyo and Osaka District Courts revealed their second proposals for settlement along with "Statements of Opinion on the Second Proposals for Settlement" ("Second Statements of Opinion"). The second proposals dealt with issues other than the lump sum settlement, namely, supplementary relief not discussed in the first proposals such as permanent measures, the treatment of those who had not yet filed suit, and so forth.

In summary, their proposals were as follows:

(a) Beneficiaries of the Settlement.

(i) This settlement shall cover the plaintiffs in the first through fourth lawsuits.

(ii) After the parties [in the first through fourth lawsuits] settle,

[58] Yakujihō § 69-2 (emergency orders).

the courts will promptly examine the evidence concerning the fact of HIV infection through the use of unheated blood products[59] as to the plaintiffs in the fifth through eighth lawsuits, and will expand the scope of the settlement to them.

(iii) For those infected but yet to sue, and for their survivors, the courts will await the commencement of their actions, then examine the evidence concerning the fact of HIV infection through the use of unheated blood products,[60] and will expand the scope of the settlement to them.

(b) Health Maintenance Allowances.[61]

(i) The defendant government shall continue to pay health maintenance costs as before to those who are infected with HIV but have not yet developed AIDS symptoms, pursuant to the "Guidelines for Implementing Research Activities for the Purpose of Contributing to Prevention of Development of AIDS in Those Who Became Infected with HIV through Blood Products," and shall make every effort to amplify such payment.

(ii) Following the settlement, the defendant government and the pharmaceutical firms shall make monthly payments of ¥150,000 [about $1,200] per person to all those who became infected with HIV through the use of unheated concentrated blood products[62] and have developed AIDS. The defendant government's share of such payment shall be forty percent. The defendant government shall handle this matter within the framework of the Public Finance Act.[63]

(c) Attorneys' Fees (omitted).

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[59] For victims of secondary infection, the courts will examine the evidence concerning how each became infected.

[60] For victims of secondary and tertiary infection, the courts will examine the evidence concerning how each became infected.

[61] This is a provisional title.

[62] The victims of secondary and tertiary infection are also included.

[63] Zaiseihō [Public Finance Act], Law No. 34 of 1947.

(d) Apportionment of the Defendant Pharmaceutical Firms' Share.

[Each of the defendant pharmaceutical firms shall pay] the pro rata amount calculated on the basis of its share as of 1983 in the unheated blood products market in Japan.

(e) The Friendship and Welfare Foundation's Relief Project.

(i) The Friendship and Welfare Foundation's relief project for those infected with HIV shall be continued for the time being following this settlement; however, [the persons concerned] shall study terminating the project, with a goal of about the year 2001.

(ii) Following the settlement, the defendant government shall bear forty percent of the expenses of this relief project.

(iii) Amounts received by a claimant from the Friendship and Welfare Foundation after this settlement has been reached shall be subject to offsetting, so the entire amount shall be subtracted from the amount of the lump sum settlement.

(f) Other Permanent Measures.

The defendant government[64] shall continue negotiations with those infected with HIV including the plaintiffs, hear their opinions, and diligently strive to take appropriate measures with respect to medical care for HIV victims, and related issues, such as setting up an HIV research and treatment center, making the selected key hospitals ready for AIDS patients, designating more key hospitals, making the national health insurance fully applicable to hospital charges for all types of wards,[65] reimbursing the medical expenses of the victims of secondary and tertiary infection, and recognizing individuals with HIV as physically disabled.

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[64] I.e., the Health and Welfare Ministry.

[65] [Translator's note: The original text says "*sagaku beddo no kaishô*," which literally means "to do away with beds for which extra charges apply."]

(2) The contents of the "Second Statement of Opinion" issued by the Osaka District Court with its second proposals for settlement were as follows:

> (i) To start with, the "Second Statement of Opinion" mentioned the parties' discussions and efforts toward settlement following the courts' first proposals. It indicated that the court was convinced that, in light of the pathetic situation of the victims and their families that the court had had a chance to observe during the negotiation process, there was no way to resolve this dispute other than through settlement, which should make early and comprehensive relief available to all those infected with HIV, regardless of which brand of product they had used or when they had become infected.
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> (ii) Next, the court pointed out that the settlement proposals were intended to relieve the victims within the time constraint of early relief by settling their claims in the form of damages in tort, and that, for this reason, there were limitations in terms of encompassing particular welfare measures in various areas. The court recognized that it would be impossible to solve all the problems conclusively in this settlement, especially with regard to the arrangement and reinforcement of medical care, and hoped that the government would do its best to improve the situation.
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> (iii) The court also emphasized that every effort must be made to eradicate societal discrimination against individuals with HIV.
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> (iv) Furthermore, the court stated that special consideration and sympathy were due to plaintiffs who were the survivors [of AIDS victims], but requested their special understanding of the fact that the suggested amount of the lump sum settlement was equal for each of the claimants because the living victims might also have to unavoidably share the same cruel and tragic fate in the future, and to provide comprehensive relief for all the victims without delay. The court hoped that the survivor plaintiffs would understand.
>
> (v) Finally, the "Second Statement of Opinion" requested that the defendants, as those responsible for aiding the victims and solving

this problem, reflect seriously on themselves, make a renewed resolution to ensure the safety of pharmaceutical products, and unhesitatingly accept the courts' proposals.

(3) The second proposals for settlement presented a plan consisting of relief not mentioned in the first proposals, such as the so-called permanent measures, litigation costs, including attorneys' fees, and the treatment of the victims yet to file suit. Among these, the contents of the permanent measures would have been difficult to order through adjudication.[66] It was on this point that advantages of settlement existed, in addition to the speediness of the recovery. It is true that there were limitations, in that the proposals did not cover welfare measures, such as reimbursing hospital charges for all types of wards, setting up an HIV research center, and designating key hospitals, but still, it seems reasonable to say that the proposals encompassed much more substantive steps toward a complete solution than a judicial decree could have ordered.

Further, that the courts proposed that the defendants defray litigation costs including attorneys' fees, together with an abundance of expressions implying the defendants' legal responsibility, which can be found throughout the "Second Statements of Opinion," may be yet more evidence showing that this settlement presupposed the defendants' legal responsibility.

Yet it is regrettable from the victims' point of view that, as a practical matter, only those who have already developed AIDS are eligible for the [monthly] health maintenance allowances, because adequate treatment is indispensable to retardation of the development of symptoms, and health maintenance allowances seem to be necessary in order to enable and to motivate individuals [with HIV] to seek such medical treatment.

IV. THE SETTLEMENT AND ITS OVERALL EVALUATION

(1) On March 29, 1996, the plaintiffs, the defendant government, and the five defendant pharmaceutical firms reached a settlement. This settlement was based on the "Statements of Opinion" issued with the courts' first proposals for settlement and the "Second Statements of Opinion" issued with their second proposals for settlement.

[66] Courts may not approve periodic payments as damages, for example.

The terms of the settlement dealt with the lump sum settlement, attorneys' fees, filing fees and other litigation costs, methods of payment, health maintenance allowances, and plaintiffs' renunciation of remaining claims. Basically, the terms were the same as those suggested in the courts' first and second proposals.

(2) Upon settlement, the parties exchanged memoranda, confirming that:

(a) The Health and Welfare Minister and the pharmaceutical firms promised as outlined below:

> (i) The Health and Welfare Minister and the pharmaceutical firms shall sincerely and solemnly accept the courts' first and second "Statements of Opinion," recognize and reflect on their grave responsibility concerning HIV transmission, and apologize to the victims from the bottoms of their hearts for having caused enormous injuries, both physically and spiritually.
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> (ii) The Health and Welfare Minister shall deeply reflect on the fact that, despite firm promises to do his best [to prevent future such tragedies] when settling the cases of the victims of the harmful side effects of thalidomide and chinoform, the Ministry once again let tragic injuries occur. The Health and Welfare Minister shall do his best to clarify the truth further, and shall make a definite promise afresh to exercise the various powers given to him in order to make every effort to keep such injuries from happening again.
>
> (iii) The pharmaceutical firms shall sincerely recognize their duty to supply safe products to consumers, and shall make a definite promise to make their best and utmost efforts to keep tragic injuries due to pharmaceutical products, as in the present case, from ever happening again.

(b) The parties reached agreement concerning the parties to be compensated, the lump sum settlement, health maintenance costs, [monthly]

health maintenance allowances for those suffering from AIDS, how the five pharmaceutical firms would make payment, and the treatment of the Friendship and Welfare Foundation's relief project. Among other matters also arranged were the following permanent measures:

> (i) The Health and Welfare Minister, while listening to the opinions of the plaintiffs, shall make efforts to take appropriate measures concerning the enhancement of medical care for those infected with HIV.
>
> (ii) The Health and Welfare Ministry shall create a forum for discussing with those infected with HIV, including the plaintiffs, medical care and related matters for those with HIV, such as setting up an HIV research and treatment center, designating key hospitals and improving the conditions thereof, reimbursing hospital charges for all types of wards, and recognizing the victims of secondary and tertiary infection as physically disabled.
>
> (iii) The pharmaceutical firms, too, shall make efforts to enhance the quality of medical treatment for those infected with HIV.

Further, an agreement was also reached, basically following the courts' proposals, as to the treatment of victims yet to file suit, attorneys' fees, and filing fees and other litigation costs.

(3) Thus, the HIV litigation came to an initial conclusion. In closing, I would like to discuss, in part reorganizing what I have already stated, how we should appraise overall such dispute resolution through settlement.

First, it must be pointed out that, considering the urgent need of relief, it was, in a sense, out of necessity that this litigation ended in settlement, because, as the "Statements of Opinion" noted, the number of the victims of the HIV incident amounted to so many as 1,800 to 2,000, and it was imperative that immediate relief be given, in light of the sad reality of the disease that all these victims would develop AIDS, experience various symptoms, and die. Even if some of the victims had won a lawsuit, their

suffering would have been multiplied during the defendants' appeals to the High Courts and then to the Supreme Court; besides, those who had yet to sue would have had to initiate suit from the beginning. Given such circumstances, it seems fair to say that a framework for a total resolution through settlement would have been needed at some stage [in any case], as evidenced, for example, by our experience in the lawsuits concerning mercury poisoning in Minamata and subacute myelo-optico-neuropathy (SMON).[67] It was significant for purposes of providing relief to the victims that this litigation came to a close before formal judgment was rendered, even though the trials had already been finished. The courts' efforts, in addition to those of the victims, their attorneys, and their supporters, must be especially noted.

Secondly, resolution through settlement was necessary also in terms of the contents of relief suitable for the injuries in question. As is widely known, under current [Japanese] tort law, damages compensation is to be made by means of one-time payment, and although some scholars suggest that periodic payments ought also be allowed, the courts have yet to endorse them. Moreover, in this particular case, not only cash payment such as health maintenance allowances, but also many nonpecuniary permanent measures were called for, such as setting up an HIV research and treatment center, enhancing the quality of key hospitals, reimbursing hospital charges for all types of wards, defraying medical costs of victims of secondary and tertiary infection, and recognizing those with HIV as physically disabled. These are steps that cannot be ordered by court decision under the present legal system, which may have been another reason that settlement was found necessary. Yet, although the settlement did stipulate monthly health maintenance allowances, even though insufficient, all the other measures were left to future talks. It is true that creation of a forum itself can be seen as a fruitful result of the settlement, but this is still [just] a starting point. It is essential that henceforth the permanent measures for remedying the victims' situation be implemented one after another.

Thirdly, judging from the above, this settlement, looked at as a whole, can be characterized as one that aimed at a "supralegal" resolution:[68] it

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[67] *See* AWAJI TAKEHISA, SMON JIKEN TO HŌ [THE SMON INCIDENT AND THE LAW] (1981). [Note 4 in the original article.]

[68] I presented a conceptual framework for disputes over pollution in Awaji Takehisa, *Kôgai funsô no kaiketsu hôshiki to jittai, in* 4 CHŪSHAKU KŌGAIHŌ TAIKEI [1] (1973). In the book cited *supra* note [67], I used this framework as a perspective for analyzing various issues, and actually examined the SMON incident. Also, I discussed the categories of recent mass toxic tort litigation that have ended in settlement,

sought, based on the [defendants'] legal responsibility indicated in the courts' "Statements of Opinion," relief that could not have or could only with difficulty have been obtained under current law. Whether it will have much substance or not, however, is up to the parties' efforts[69] and the support of public opinion in the future. In this respect, the settlement was but the first step to a [complete] solution.

V. CONCLUSION

Although there are some reservations as mentioned above, the dispute has been solved by [the defendants' promises to pay] compensation for the victims' losses and [to provide] other relief measures. Yet there is no genuine solution unless we make sure that tragic injuries due to pharmaceutical products, as occurred in this incident, will not be repeated. In the "written vow" that the government and the pharmaceutical firms submitted when they assented to the settlement proposals, they promised never to let such injuries happen again. But words alone are not enough. What is wrong with the current law and the legal system must be examined hereafter,[70] but prior to that, [all] the facts of the HIV incident must be elucidated and the responsibility for this incident must be clarified. I hope that the facts will be brought to light in the Diet, in the media, and in court, when necessary.[71]

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in Awaji Takehisa, *Kôgai, kankyô funsô*, 48 HÔSHAKAIGAKU 93 (1996), focusing on advantages of such settlements. [Note 5 in the original article.]

[69] Particularly, governmental policy concerning how to improve the current system and how to construct a new system in order to accomplish the various relief measures is of fundamental importance.

[70] I understand that JURISUTO plans to publish more articles on this theme.

[71] [Translator's note: *See supra* note 9.]