Chief at Company Y, was sent to the company to cover for him. Nominally, Mr. Ishimaru was placed in charge of accounting; in fact, he had responsibility for all of the company's operations. Business policies including management decisions were frequently decided by Mr. Ishimaru and the Plaintiff. Also, around May 1987, the Plaintiff received a raise of more than ¥20,000 to ¥41,000 per month.

Under the circumstances described above, the Defendant increasingly felt like he was being excluded from important decisions, in spite of the fact that he was Chief Editor. Subsequently, after reviewing the company's financial condition for the period ending in May, management blamed the Defendant for the company's lackluster performance, and rejected his proposal for lifting the company out of trouble, which was to distribute Campus Fukuoka for free. As a result, the Defendant became so worried that he contemplated resigning.

6. Around January 1989, the Plaintiff tentatively broke up with the manager of the travel agency, and around May of the same year, she terminated the relationship. The travel agency's advertisements continued to appear in Campus Fukuoka through April 1987, but they ended with the July 1987 issue.

7. In 1987, a Mr. Shima, who had significant work experience as a major advertising firm, was asked to turn around the management of the company. He took the job under the title of Managing Director. However, Shima was in fact the highest decision maker in the firm, with authority to make all ordinary business decisions that did not require representative authority. Soon after Shima joined the company, Mr. Ishimaru returned to Company Y.

8. In order to turn around the company, Shima established a system of management in which his decisions would be conveyed through the Chief Editor, Defendant Heikawa. Before then, there had not been a clear chain of command to implement business decisions. Shima also adopted the Defendant's proposal to make Campus Fukuoka a free newspaper.

The Defendant, who once considered leaving the company because he felt alienated from the decision-making process, now had his confidence restored. Moreover, he assumed responsibility over the company's primary business (editing Campus Fukuoka) and delegated work related to the production of AN, which is subcontracted from Company Y to the Plaintiff.

9. From then on, major decisions were made by Shima and Defendant Heikawa.

The company, however, was still experiencing financial difficulties in December 1987, and it was uncertain whether it would be able to pay bonuses to employees. When the Defendant met with the Plaintiff to discuss the company's financial condition, the Plaintiff informed him that another magazine was trying to hire her away from the company. Heikawa strongly encouraged the Plaintiff to quit.

After the meeting, the Plaintiff became aware that the Defendant wanted to force her to resign from the company, and she became sensitive to everything that he did and said.

10. Since February 1988, the Defendant had been reporting to Shima about the deterioration in the working environment. On March 9, Defendant told Shima that he believed the Plaintiff should quit. Shima responded by pointing out that the Defendant had no authority to make decisions about personnel. Shima instead suggested he discuss the issue thoroughly with the Plaintiff and try to work things out.

The Defendant called the Plaintiff on March 16, and demanded that she quit. He told her that he knew she had had a relationship with the branch manager of the travel agency, and that the travel agency decided to discontinue its advertisements because she had ended the relationship. He mentioned several specific names such as Mr. Sekido, a reporter for a sports newspaper, and Mr. Hijiki, a free-lance writer, and told the Plaintiff that he knew that she had had relationships with them as well. Heikawa also alleged that prank phone calls that the company had been receiving since September 1987 were related to the Plaintiff's relationships with men. He claimed that she was disrupting the company's business and demanded that she quit.

11. The Plaintiff rebuked him and argued that these were just rumors spread by the Defendant himself, and that it did not make any sense for her to quit because of the rumors. Moreover, the Plaintiff demanded that he apologize to the affected individuals.

On March 9th, the Defendant even appealed to Shima, asking him to order the Defendant to apologize. Shima replied that he could not force the Defendant to apologize unless it was certain that he was the source of the rumors. Shima suggested that the only way to clear up the mistrust was for the two of them to discuss the issue thoroughly among themselves.

The Plaintiff also asked Mr. Otomo, the representative director of the company, to help her. However, he simply told her not to take what had happened so seriously.

Around the same time, the Plaintiff consulted with several of the company's employees and a Mr. Nakagawa, an employee at a record company. Through her conversations, the Plaintiff discovered that the Defendant had told Nakagawa at a party held sometimes around the end of 1987 that the Plaintiff had an affair with a sports reporter. She also discovered that the Defendant had described the Plaintiff's private life in very negative terms to a female employee who joined the company in January 1988.

[At another point in the opinion, the court found that the Defendant had told the new employee that the Plaintiff was sexually active, led a wild private life, and was better suited to work as a bar hostess or prostitute (in Nhật case) than at the firm. The court also found that the Defendant continually criticized the Plaintiff's life style, and told Shima and others that a novel she had written must be a pornographic novel based on her own experiences.]

The situation deteriorated further over the next few months, and other employees complained that the hostility was interfering with their ability to work. Shima's efforts to assure plaintiff's anxiety.

15. Shima reported the above-described events to the representative director and company management during the morning of May 24, 1988. After much discussion, they concluded that Shima should meet with the Plaintiff and the Defendant and discuss the matter with each separately if they could not work out some mutual understanding, there would be no recourse but to ask one of them to resign.

That afternoon, Shima met first with the Plaintiff and asked her whether there was any room for compromise. The Plaintiff continued to demand that the Defendant apologize to all those affected by the rumors. The Plaintiff also demanded that Shima confirm her side of the story by contacting people outside of the company.

In reply, Shima told her that she would be asked to leave the firm if the talks did not progress. The Plaintiff then expressed her intent to resign, whereupon Shima ended the meeting. Next, Shima told the Defendant that he was going to meet with him, that the Plaintiff had offered to resign. Shima suspended the Defendant from work for three days on the assumption that both parties were to blame.

14. Thereafter, the company paid the Plaintiff a severance fee of ¥112,150, which amounted to about one-month's salary, and a ¥50,000 bonus.

[D. Defendant Heikawa's Liability]

1. Defendant Heikawa made statements both within the office and in other places connected to work that paved into Plaintiff's private life and affairs. As a result, he created a situation in which it was uncomfortable for the Petitioner to work. Moreover, if the Defendant intended to create such an atmosphere, or at least could have foreseen that such an atmosphere would result, because such actions degraded the Plaintiff's character and hurt her feelings, he infringed her right to work in an environment conducive to work. Thus, we must conclude that Defendant bears tort liability under Arti-
... Viewing the series of actions of the Defendant described above, first, there are remarks made to people within the company that make Plaintiff's private life, especially her relationships with men, seem disorderly and that are critical of her character as a working woman. Second, identifying the names of specific men with whom the Plaintiff has had relationships (especially, if such men have a connection with the company) and spreading rumors about the Plaintiff to people with whom the company does business, are acts that degrade the reputation of the Plaintiff. Some actions made fun of the Plaintiff directly about the way she chooses to live, others relate to the Plaintiff's private life, including her relationships with men. All, however, are acts that degrade the reputation of the Plaintiff as a working woman. In addition, repeating these things in Shima, a superior, as if they were true, ultimately resulted in her quitting. It must be said that these acts were against the wishes of the Plaintiff and infringed upon her dignity and other personality rights. Moreover, relations between the Defendant and the Plaintiff became severely strained after he ordered her to quit in March 1988.

The work environment became so uncomfortable as to cause part-time workers to complain to Shima. These facts make it clear that the series of acts described above caused the deterioration in the work environment for the Plaintiff. We conclude that the Defendant easily could have foreseen that his actions were likely to cause this result.

Of course, the words and actions of the Defendant are not solely responsible for the deterioration in the work environment. Conscious of her own abilities and the lack of responsibility that the Defendant felt toward his job, the Plaintiff thought of Defendant Heikawa as a rival. The fact that she hoped to be at the center of the business and inserted herself in a position where she would be able to cultivate relationships with people with whom the company did business, as well as her own attitude, behavior and temperament... contributed greatly to the conflict between them. In deciding the matter before this Court, we must fully consider these additional circumstances. It is possible that the damaging remarks were exchanged between the Plaintiff and Defendant Heikawa. Nevertheless, considering the position of working women in modern society and the prevailing attitudes toward women held by men who occupy management-level positions, we must conclude in this case that it was wrongful to criticize the Plaintiff's private life, including her relationships with men, as a means to resolve their conflict and to force her out of the company.

3. Considering the series of acts described above, Defendant Heikawa cannot escape tort liability for his actions against the Plaintiff.

E. Defendant Corporation's Liability

1. Employer liability [respondent superior] for the acts of defendant Heikawa. As set forth above in Section D, the series of acts directed against the Plaintiff were made by a person who stood in the position of a supervisor at work, and such acts were related, in whole or in part, to the job. The series of acts involved the Plaintiff, Defendant Heikawa's supervisor, employees and part-time workers who worked under Heikawa, and employees of the company's clients. We find that the series of acts were carried out "in connection with the execution of business." As Heikawa's employer, the Company is liable under the theory of respondent superior [طبقية عامل].

2. Employer liability [respondent superior] for the acts of Managing Director Shima and others. We consider below the Plaintiff's assertion that the company is liable under the theory of respondent superior because the actions of Shima and others, combined with the acts of Heikawa, give rise to joint tort liability.

(i) Employees have duties that arise out of the common social understanding of the relationship between employer and employee. An employer owes a duty of care with respect to the work environment so that the life and health of its employees are not damaged in the process of providing labor. In addition, it is also understood that there is a duty to maintain an environment conducive to work for the employees, by preventing occurrences that infringe on employees' dignity or pose a serious obstacle to the provision of labor, and by responding appropriately to such occurrences. Where a person in a supervisory position over employees neglects this duty of care, that person commits a tort against the employees, and the employer also bears tort liability under Article 714 of the Civil Code.

(ii) As we determined above, Managing Director Shima was in fact the person with ultimate responsibility within the company even though he did not have representative authority; the Defendant Representative Director is, as the name implies, a representative director. Both were in supervisory positions with respect to the Plaintiff, so it can thus be said that both have a duty to favorably regulate the work environment...

(iii) The facts indicate that Shima and the Representative Director neglected their duty to regulate the work environment. Moreover, despite that fact that the Constitution and related statutes and ordinances require men and women to be treated equally in employment relations, [Shima's and the Representative Director's] attempts to adjust employment relations consisted principally of requiring the Plaintiff, who is female, to make concessions and sacrifices. We find this to be wrongful conduct, and accordingly also find the company liable for these tortious acts.

F. Petitioner's Damages

The Plaintiff suffered damage with Defendant Heikawa in the office because he was judgmental about her private life, including her relationships with men, and spread rumors about her relationships with men. She was asked to quit, and ultimately things reached the point where she did quit. Spreading rumors and criticism regarding a working woman's private life, including her relationships with members of the opposite sex or private sexual matters, and making someone feel like an outcast in the office, causes emotional suffering, creates anxiety and reduces a person's desire to work. In the end, it invokes the consequence that the person will lose their job. This case followed a similar pattern. The Plaintiff lost a job toward which she was devoted and enthusiastic. In light of the fact that this case involves personality rights such as respect for women and sexual equality, we cannot view lightly the degree of illegality [of Defendants' conduct]. We can imagine the Plaintiff suffered considerable mental anguish as a result of the Defendants' actions.

On the other hand, after Defendant Heikawa ordered her to quit, the Plaintiff became angry and demanded that Heikawa and others apologize to her and to those with whom they alleged she had had relationships. In addition, she maintained a defiant attitude and failed to show any willingness to discuss matters with Respondent Heikawa calmly. Moreover, the continually questioned Respondent Heikawa's ability relative to her own over each and every thing that she did. She also fought hard to be put in charge of editing work at the Company and thought of Respondent Heikawa as a rival. She herself decided to network with part-time workers, clients and other people associated with the Company and created factions within the company [for strategic reasons]. On occasion, she would attack Respondent Heikawa. As such, we find that the Petitioner played a part in escalating the conflict between herself and Heikawa. Finally, the Petitioner herself disclosed some of the information regarding her relationships with members of the opposite sex.

2. Considering these circumstances, as well as the various facts recognized above, we find that ¥1,900,000 is an appropriate amount of damages to compensate the Petitioner for her emotional suffering. [The court also included ¥150,000 for attorney's fees.]
THE HIV LITIGATION AND ITS SETTLEMENT
[IN JAPAN]

Awaji Takehisa

Translation by Keisuke Mark Abe

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) were imported from the United States and administered by transfusion to hemophiliacs. This was termed the HIV-,

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

2 Professor of Law, St. Paul University. The author wishes to thank Suzuki Toshihiro and other members of counsel for the plaintiffs in the Tokyo HIV litigation for providing him with the materials including their trial briefs. [Postscript in the original article.]

3 Ph.D. Candidate, Graduate School of Law and Politics, I.B.L., L.L.M. (University of Tokyo); LLM. (Harvard). The translator is not related in any way to Abe Takehisa, former head of the Health and Welfare Ministry’s AIDS research team. See infra note 25 and accompanying text.

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 perinatal infection. See, e.g., Yamamuro Hirokuni, Officials Must Account for Their Actions, DAILY YOMURI, 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, and against the Japanese government, which is responsible for regulating pharmaceuticals. 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. From the government, the plaintiffs sought to recover damages on the basis of negligence.

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.

Under these circumstances, the consolidated trial in Tokyo ended in March 1995, and the consolidated trial in Osaka in July. On October 6, 1995, while the 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. 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, 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.

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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9 The ministry in charge of this matter is the Health and Welfare Ministry.
10 MINO § 709.
11 Kokka baisōhō [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 Takashi, infra note 25, three former presidents of Green Cross Corp., and Matsumura Akihito, former director of the Biologics and Antibiotics Division (seibutsu seni kacho) 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 YOMURI, Oct. 10, 1996, at 2; DAILY YOMURI, 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 YOMURI, Oct. 24, 1996, at 2. Prosecutors decided not to seek criminal charges against Gunji Atsumi, infra note 24, Matsumura’s predecessor at the Division. Id.]
12 The NHK [national public television] report was particularly outstanding.
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 zasshoku: wa shakai to sono no go no mondai, 498 HOGAKU SEIKAN 4 (1996), the plaintiffs’ trial briefs, the defendant government’s trial briefs, the defendant pharmaceutical firms’ trial briefs, and articles that appeared in ASASHI SHIBUN, YOMURI SHIBUN, and MAINICHI SHIBUN. 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 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 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, was approved in 1970 under the Pharmaceutical Affairs Act for purposes of treating type A hemophiliacs, and was put in use. Ordinarily, cryo is made from one or two donors' blood.

Subsequently, pharmaceutical firms started producing blood products that densely concentrated these blood-clotting factors. 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, 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 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., 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 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,
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. 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, 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. Subsequently, in May 1985, two months after the first Japanese case of AIDS was officially announced, 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, 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.

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 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. 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.

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

\[\text{\footnotesize{13 ASASHI SHIMBUN, Mar. 20, 1996.}}\]

\[\text{\footnotesize{14 YOMURI SHIMBUN, Feb. 26, 1996.}}\]
conflicting opinions were expressed. In order to examine this issue, a subcommittee on blood products was set up under the research team. 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. By May 1985, the domestic firms had developed the heat treatment technology, so applications for approval of heated blood products were filed, 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.

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. 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.


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.

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 to all claimants alike, including the plaintiffs in this case.

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

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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 the 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.
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," and that, when authorizing the manufacture of a pharmaceutical product, the Health and Welfare Ministry should review its "side effects." 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. 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. [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 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 Teikyô 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 responsible 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

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.


49 Of course, it would be necessary that phrases like “has a responsibility to” (sekimu ga aru) be replaced with [more formal language] such as “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. [MNPO § 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, or at least gross negligence, could have been established. For example, Green Cross’s U.S. subsidiary had been sending information on the risk of unheated blood products to Green Cross since around the end of 1982. 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 and the Health and Welfare Ministry’s regulatory powers which ought to have been applied in this case, 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 to suspending the sale of unheated blood products, 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 responsibility.”

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,
the courts will promptly examine the evidence concerning the fact of HIV infection through the use of unheated blood products 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, and will expand the scope of the settlement to them.

(b) Health Maintenance Allowances.

(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 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.

(c) Attorneys' Fees (omitted).

(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 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, reimbursing the medical expenses of the victims of secondary and tertiary infection, and recognizing individuals with HIV as physically disabled.
(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 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.

(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 when regard to the arrangement and reinforcement of medical care, and hoped that the government would do its best to improve the situation.

(iii) The court also emphasized that every effort must be made to eradicate societal discrimination against individuals with HIV.

(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. 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, 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.

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* 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.

(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).\textsuperscript{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.\textsuperscript{68} It 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\textsuperscript{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,\textsuperscript{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.\textsuperscript{71}

\textsuperscript{67} See Awaji Takehisa, SMON IKKEN to Hō [THE SMON INCIDENT AND THE LAW] (1981). [Note 4 in the original article.]

\textsuperscript{68} I presented a conceptual framework for disputes over pollution in Awaji Takehisa, Kōgai funsō no kaiseki to shiritori to jittai, in 4 Chūshaku Kōgaiho 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, in Awaji Takehisa, Kōgai, kankyō funsō, 48 Hōshakaigaku 93 (1996), focusing on advantages of such settlements. [Note 5 in the original article.]

\textsuperscript{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. I understand that JURUSUTO plans to publish more articles on this theme.

\textsuperscript{70} [Translator's note: See supra note 9.]
Notes


2. We have noted a number of times, euthanasia is generally prohibited in the West (outside of the Netherlands and Oregon), while withdrawal of treatment is generally permitted. It is not, of course, necessary to observe this distinction. The Japanese case that follows both accepts active euthanasia, in principle, and takes a very conservative view (by Western standards) of withdrawal of treatment.

Tokai University Hospital—Euthanasia Case.

Judgment of Yokohama District Court, March 28, 1995, 1530 Hanrei Jihō 28 (Japan v. Tokunaga), (Tokai University Hospital euthanasia case)

Translated and edited by Robert B. Lefar

[Translator's note: This case was the first case in Japan in which a physician was prosecuted for an act of euthanasia...The patient, Mr. Katsunora, age 57, was terminally ill with bone marrow cancer. He was hospitalized in Tokai University Hospital at the end of 1990. His three physicians were Dr. Nozaki, Dr. Noguchi, and the defendant, Dr. Tokunaga.]

Facts

Dr. Nozaki, the original attending physician, informed the patient's son and wife that the patient, Mr. Katsunora, had untreatable bone marrow cancer. The son strongly requested that his father be informed of the cancer diagnosis; so the patient was told there was an 'insufficiency of bone marrow function.'

The patient's condition worsened in late March 1991. The defendant, Dr. Tokunaga, was told by Drs. Nozaki and Noguchi about Mr. Katsunora's condition and prognosis, and about the family's request that the patient not be informed of his diagnosis. On April 5, the patient began vomiting blood, and on April 8 a plasma exchange was commenced. [There follows a day-by-day account, somewhat excerpted, of his last illness.]

April 9: The patient was scarcely conscious, and could respond only to simple commands. At 9 am his wife and son said to Dr. Noguchi: "The patient didn't sleep at all last night. He is complaining of pain from the Foley catheter. He's suffering so much we can't watch. We want the plasma exchange stopped. Take out the I.V. and the Foley catheter, and stop all treatment. The patient understands what's happening. This is an incurable illness, there's no point in treating it any more; please don't keep him suffering."

Dr. Noguchi told Dr. Tokunaga of this request by the family to cease treatment; Dr. Noguchi also presented it to the senior physician on his rounds. But the family withdrew the request later after hearing an explanation from the senior physician.

April 10: The patient could not respond when spoken to, but his condition had stabilized. At 6:30 pm the wife and son asked Dr. Noguchi again to stop treatment and to discontinue the I.V. and catheter. Despite his attempts at persuading them to continue treatment, they tenaciously refused to acquiesce. After an hour of his persuasion,
Dr. Tokunaga said, "Taking him off the I.V. means stopping nutrition and hydration, and that would shorten his life. Wouldn't that be too selfish, to let him die? I can't do that. As a doctor I'm going to fight it to the end."

Defendant on the one hand as a doctor believed he couldn't stop treatment. On the other hand, he understood the family's feeling of life with death only a day or two away, advancing that death by removing the I.V. and Foley catheter that the patient seemed to dislike and permitting him to die naturally, probably wouldn't contravene the patient's own wishes. All these things filtered through the doctor's mind. [Translator's comment: The judge is exercising a good deal of creativity in setting out these facts.]

So Dr. Tokunaga finally reached the conclusion that removing the life-sustaining treatment and speeding up the patient's death would be acceptable, and he answered the family: "All right. I understand." He went back to the nurse station, and said to Head Nurse Ito, "I've been told by the family that they want all treatment stopped. I've tried over and over to persuade them otherwise, but they won't listen. So we'll stop all treatment, and remove the I.V. and Foley catheter." Hearing this, Nurse Ito said, "Let me try to talk with them." She did so, but to no avail.

At 11:20 am defendant Tokunaga told a nurse to stop all treatment, and wrote the order in the chart. About 1:30 pm, the nurse disconnected all the equipment.

The son thought that the father would die naturally as though in his sleep that night. He stayed in the hospital room with him. But the father's breathing became more labored still, weighing on the son's mind. (The wife, at the son's suggestion, had gone home in the afternoon to rest.)

About 3 pm, Dr. Nozaki came by and was surprised to find the I.V. and catheter out. Thinking that Dr. Tokunaga, to whom he had turned over the patient's care, had given in to the family's requests, he called out to Dr. Tokunaga at the nurse station, "I see you've stopped the I.V." Dr. Tokunaga responded: "I tried to persuade them, but they wouldn't listen, so I stopped it." Dr. Nozaki, acquisitive, then left for a conference in Kyoto.

About 3 pm, Dr. Tokunaga checked the patient. The breathing tube was in, and the EKG monitor was attached. The patient's level of consciousness was Level 6: no reaction to pain stimuli, no consciousness. He thought the patient probably would die that day or the next. At about 4 pm, he met Dr. Mishima of the same department and talked as he had told Mishima that he had stopped treatment. Mishima replied, "That ought to shut the family up."

The son, seeing his father apparently suffering with heavy breathing and wanting him to die quietly as though in his sleep, called Dr. Tokunaga to the room about 5 pm. "He's suffering. I want you to take out the breathing tube." Dr. Tokunaga replied, "I can't do that. There's a danger that his tongue will block his throat and he'll stop breathing."

The son renewed the request. Dr. Tokunaga thought, it's all right with the son if his father dies. He already agreed to his request to disconnect the I.V. and catheter. So at 5:45 pm, he took out the breathing tube.

The patient's labored breathing continued. About 6 pm the son called Dr. Tokunaga to the bedside again. "I can't stand to listen to his breathing. I see him suffering like this. Please put him to rest. Please let me take him home quickly." Dr. Tokunaga, thinking that at least he could quiet the father's breathing, said "I understand." He went back to the nurse station, considering what drug would suppress this labored breathing.

He decided on Horizon, an analgesic with the side effect of suppressing breathing, knowing the drug might hasten the patient's death. He had Nurse Kadogawa prepare twice the usual dose: 4 ml. At 6:15 he injected it into the patient's left arm. The son silently watched him from the bedside.

After watching for nearly an hour after this injection, the son, seeing that his father's labored breathing continued unchanged, called loudly for Dr. Tokunaga: "He's still breathing. I want to take him home quickly." Dr. Tokunaga went back to the nurse station, filled a syringe himself with double the normal dose of the drug Sereneus, and at about 7 pm injected it into the patient's left arm. (Sereneus also has the side effect of suppressing breathing.)

The son, after watching the injection, asked "How long will it take?" Dr. Tokunaga replied: "His heart's really strong. Maybe an hour or two."

After the Sereneus injection, Dr. Tokunaga, seeking to forestall any more requests from the son, called him out of the hospital room. "You're asking me to kill him with these drugs. Well, the law doesn't allow it, and as a physician I can't do it." The son just listened silently.

The son, seeing the father unchanged after the second injection, suspected Dr. Tokunaga of trying to fool him with meaningless injections. He paged Dr. Tokunaga, who was in his car to get some dinner outside the hospital. Dr. Tokunaga turned and came back without getting dinner. The son confronted him at the nurse station angrily. "What are you up to, doctor? He's still breathing! I want to take him home before this day is over."

Dr. Tokunaga felt that he could not escape from the unusually persistent demands of the son. He went into the nurse station without answering, worried about what to do. He felt as though as much as he tried to refuse the son's requests, he couldn't keep doing so forever. He was physically and mentally exhausted. He finally decided to do the son's bidding, and make the patient die.

He decided to use a drug that would make the patient's heart stop. Looking in the bookcase at the nurse station, he saw in a drug compendium that Wasoran, used for circulatory conditions, had the side effect of transient heart stoppage. He decided to use it. But that alone might not kill the patient immediately. So he decided to add KCl (potassium chloride), which causes damage to the heart's electrical function, to the mix.

Usually potassium chloride is diluted and given patients intravenously. But Dr. Tokunaga decided to inject it in undiluted form. He asked Nurse Miyoko Takanishi if they had potassium chloride and Wasoran available. She said "There's some potassium chloride, but no Wasoran." But she knew about his trying the other two drugs, and she acceded to his request. She wrote up an order for Wasoran to the hospital pharmacy, and gave it to Dr. Tokunaga. He got it from the pharmacy.

Dr. Tokunaga put 5 ml of Wasoran—twice the usual dose—into a syringe. He put 20 ml of potassium chloride in another. He went to the patient's room. The patient was breathing laboriously. The son watched him silently.

Facts Constituting the Crime

The defendant, on April 13, 1991 at about 8:35 pm, in Ishara City, Kanagawa-ken, at Tokai University Affiliated Hospital, 6th Floor Room 14, injected the patient first with Wasoran; upon seeing that had no effect, he injected 20 ml of undiluted potassium chloride into the patient's left arm. Nurse Kadogawa immediately noticed an abnormality on the heart monitor and shouted, "There's a ventricular narrowing." But Dr. Toku-
naga kept on with the injection. He confirmed the patient's heart stoppage on the monitor, checking for lack of a heartbeat and pulse. He said to the son "It's over." At about 8:46 pm, the patient died of heart stoppage caused by an acute high level of potassium in the blood.

Judgment of the Court

Part I. Introduction

[The court makes general observations about medical progress, euthanasia, and how this case forces us to define the legal limits; what's important about the case; the consequences of the decision.]

Part II. Requirements for Cessation of Treatment

Death must be unavoidable; the patient must be in the last stages of an incurable disease with no prospect of recovery. The cessation of treatment originates in the patient's right of self-determination and the limit of a physician's duty in cases of medical futility. This is not to recognize the patient's right to die as such, or right to choose death. It simply recognizes a right to choose the method or process of facing death. This is to prevent us from viewing death too lightly. It is desirable that more than one physician make the judgment that recovery is impossible. Also, if the treatment in question is one that has only a small influence on the patient's continued life, it should be easier to terminate the treatment than if it is in direct with the patient's death—in which latter case the patient should be actually facing death before the treatment is terminated.

It is necessary for the patient to have made an expression of intent that treatment cease, and that intent [not be revoked] at the time of the cessation of treatment. It goes without saying that it is most desirable for the patient himself to have clearly expressed that intention. The expression of intention should be based on the patient's own accurate knowledge of his disease, nature of treatment, and prognosis. For this reason the importance of informing the patient of his diagnosis and of informed consent is indicated.

However, in the great majority of cases, patients will be unable to express their intention about cessation of treatment at the time the decision must be made. Most Japanese today, we expect, would want meaningless treatment stopped, and we can expect that in future, living wills will become more prevalent. But we must consider whether substituted consent [lit. "inferred intent"—suteitetsu koto] should be recognized.

If there is a prior expression of will by the patient, whether written or oral, it is powerful proof—if near in time. But if remote in time, or vague, then the case should be treated like situations where no expression of will by the patient exists. Where no reliable expression of the patient's intent exists, it is best to rely on the family to state the patient's "inferred intent." Better this, than digging into fragmentary evidence of what the patient might have said in passing. The family is likely to know the patient's character, values, and view of human existence. The family, like the patient, should be given accurate information about the patient's condition, nature of treatment, prognosis, etc. To judge the family's ability to speak for the patient, it is necessary for the physician to know about the patient's relationship to his family, how close they are, and so forth.

The treatments that may be terminated include drugs, chemical treatment, artificial respiration, blood transfusion, nutrition and hydration—both measures for treatment of disease and life support measures. However, what treatments should be stopped, and when, are medical judgments about when the treatments are meaningless.

Part III. Requirements for Euthanasia

Conditions for active euthanasia by a physician:

a. Physical pain difficult to bear.

b. The time of unavoidable death is drawing near.

c. Methods of eliminating or easing physical pain are exhausted, and no substitute means remain.

d. There is a clear expression of intent to accept the shortening of life.

Conditions for cessation of treatment: An expression of intent by family members who can infer the patient's will, will suffice. [Moreover, cessation must be medically appropriate.]

Defendant's acts here did not meet the conditions allowing either "cessation of treatment" or "active euthanasia."

The patient had bone marrow cancer. A doctor at Tokai University Hospital received a request from the patient's son to "put him to rest," saying "I want to take him home quickly" [i.e., as a corpse].

A distinction must be made between physical suffering (whether existing or probable in the future), which can serve as a justification for active euthanasia, and mental suffering, which cannot. Judging mental suffering is too subjective; we could start to view death too lightly.

Active euthanasia is permitted as long as death is imminent. But if it is not, "indirect euthanasia" [kurusutsu-teki annakushii], in the sense of pain relief treatment with the possibility of hastening death, can be used.

The idea of allowing euthanasia is based on the concept of patient autonomy: the patient must choose whether to undergo suffering or shorten life. So an indication of the patient's will is essential. Whether a clear indication of the patient's will is required, or whether merely an inference of the patient's intent will suffice, depends on the method of euthanasia.

The court sets out three types of euthanasia:

Passive (shikkyo kureteki): the cessation of life-prolonging treatment, a non-deliberate (fusakusa) act

Indirect (kurusutsu kureteki): giving pain relief treatment with the possibility of hastening death

Active (sokkyo kureteki): treatment deliberately inviting death in order to free the patient from suffering

The permissibility of euthanasia differs according to which of the three types is in question.

The permissibility of passive euthanasia is to be judged merely as a matter of whether it is medically appropriate to cease treatment. Indirect euthanasia is permitted in accordance with the principle of patient autonomy. An inference of the patient's intent will
suffice; and this can be inferred from the family's expression of intent. Active euthanasia is permissible only when all means of removing or easing pain have been exhausted, and no other alternate methods exist. Then as the Nagoya High Court said in its December 22, 1962 judgment (Hanrei [Libro] 324:1): "It must be performed by a physician."

Active euthanasia is based on the principles of emergency refuge [kinoki no hiran] and patients' self-determination; so it is permissible only with a clear expression of intent by the patient. Passive euthanasia is permissible only if the patient is in an incurable state, nearing death, with no prospect of recovery. Some evidence of the patient's intent is required for passive euthanasia. Clear evidence of the patient's will at the time of the decision to cease treatment is desirable. It should be based on continuing consideration and accurate information concerning prognosis, accurately understood.

However, clear evidence of the patient's will is not necessary for cessation of treatment. Passive euthanasia is also based on inferences from the patient's own previous expression of will, or from the family's statement of intent. Still, to recognize that the family is properly inferring the patient's will, the family must know the patient's character and values, and must have full and accurate information on the nature of the disease, treatment, and prognosis. Moreover, the physician assessing the family's expression of will must be in a position to know both the patient's own thoughts and position concerning his disease and treatment, and the level of the patient's relationship with his family.

The conditions justifying active [or indirect] euthanasia were not met here. The fatal injection was not for the purpose of relieving physical pain, since at that time the patient was not suffering; and since the patient had never been told he was suffering from cancer, there was no clear statement available as to the patient's own intent.

Part IV. Evaluation of Defendant's Specific Acts

Removal of I.V., Foley Catheter & Breathing Tube: Both Dr. Tokunaga and Dr. Nozaki judged that the patient, as of April 13, 1991, had only a day or two to live. Other physicians said the same; even with aggressive treatment, the patient could at most have survived 4-5 days. So objectively, the patient's condition was at the stage appropriate for consideration of termination of treatment.

As for the expression of the patient's will, this patient had not been informed of his diagnosis, and had not received an accurate explanation of his condition and prognosis. At the time of decision, he was incapable of expressing his will. So we must determine whether the family could properly speak for the patient. Both the wife and son had lived with the patient for many years, and knew his character, values, and outlook on life. They kept insisting on cessation of treatment over several days. We can conclude that they were capable of expressing the patient's inferred intent. However, the family were not properly informed of the patient's inability to feel pain. On April 13, when they asked that the I.V. and Foley catheter be discontinued, they were not told that he had no response to painful stimuli. So their request cannot be considered to be properly grounded, inferred expressions of the patient's intent.

This defendant had only known the family for a short time — less than two weeks — at the time he became attending physician for this patient. There is doubt whether he really understood their position. He was not in a position to judge whether their decisions were a proper expression of the patient's intent. The patient's intent was neither expressed nor could be inferred from the family. Therefore the withdrawal of the I.V. etc. was not permitted by law.

2. The Injections of Horizon and Serenex

Not being premised either on the patient's own expression of intention nor on the patient's inferred intent stated by a properly informed family, these injections do not fall within the permitted indirect euthanasia.

3. The Injections of Wasorin and Potassium Chloride

Since the patient was feeling no pain at the time, the prerequisite for legal active euthanasia — intractable physical pain — was not met. Nor was there a finding that alternative measures were not available. Neither did the patient give express consent. The conditions for legally permissible active euthanasia were not fulfilled. Defendant pleaded that the son was an "instigator." But the court considered the doctor's higher status and position, and rejected the argument.

Reasons for Punishment

[The court concluded these illegal acts undercut trust in medicine, and speculated that doctors might start shortening the lives of patients who are not facing immediate death.]

Even though the hospital at which defendant was employed has high standards, its system for end-of-life care was deficient. The "team concept" did not function well, because of the shuffling around of staff.

The family's influence on end-of-life decisions is great. This doctor's training and experience in dealing with such situations was poor. [The court gave reasons for leniency with the punishment: e.g. the family does not hold bad feelings toward the defendant.]

Sentence: Two years, suspended. [The sentence was not appealed.]

Both Western and Japanese names are given family name last, to avoid inconsistency. Yen amounts are given in dollars at $1 = 110, an exchange rate typical of recent years.

LEXISNEXIS SUMMARY:
... Pervasive safety problems in medicine, scarcely noted a decade ago except among specialists, in the past few years have found a place on the health policy agenda of developed nations worldwide. ... Perhaps the supervising physician, who authorized the operation without requiring a more experienced surgeon to proctor it, might also have suffered some discipline. ... In the United States, what brought the problem of medical error to the forefront of public attention was epidemiological studies of hospital injury, drawn together in compelling fashion with insights from behavioral science in the Institute of Medicine report, To Err Is Human. ... A major difference between Japan and the United States in this respect is that medical malpractice liability premiums in Japan do not vary depending on the physician's specialty or geographical area of practice ... Now, at least with regard to this aspect of medical malpractice litigation, if the principle of the Saitama Medical University decision is broadly applied, the tables may well have turned: Japanese law may tilt more than U.S. law toward error information disclosure in the judicial process. ... It is possible that the threat of criminal prosecution and accompanying adverse publicity may undercut sorely needed initiatives within Japanese hospitals to perform self-critical analyses, although statistics demonstrating a recent substantial increase in reporting of medical accidents to police cast some doubt on the extent of this potential patient safety problem. ...
In Part IV, we take up criminal liability for medical error, offering an explanation for the relative prominence of the criminal forum as an accountability mechanism in Japan, and suggesting that, in some respects, medical practitioners' fear of criminal liability in Japan bears a functional similarity to American providers' fear of tort. The extent to which that fear in fact detracts from self-critical analysis and reporting of accidents, however, seems as unclear in Japan as it is in the United States. Finally, in Part V, we describe an innovative project currently under way in Japan on error investigation and dispute resolution.

We conclude that although the institutional structures of Japanese medical and legal systems present severe obstacles to satisfactory progress toward the goal of zero deaths, all nations share, nevertheless, Japanese initiatives and practices in some respects may usefully inform health policies and practices in the United States and elsewhere. Nationwide risk pooling of medico-legal liability insurance, without regard to medical specialty or geographic location, may stabilize the harmful volatility of liability premiums experienced in the United States. A recently recognized civil-law duty of error disclosure to patients may suggest analogues in American medical jurisprudence. An experiment in impartial expert investigation of suspected medical error cases may offer a useful method for speedier, more objective resolution of quality-of-care disputes. Finally, although the engagement of the criminal justice system as a quality control mechanism has serious drawbacks, in Japan, at least its looming presence has served the beneficial purposes of helping motivate medical leaders to undertake systemic reforms, and to deter medical providers' widespread practice of deceiving patients and families.

II. First Cut: Public Accountability and Public Awareness - Aoto Hospital and the Roles of the Media, Civil, and Criminal Law

In American jurisprudence, it is tort law-specifically, medical malpractice law-that casts the longest shadow over controversies relating to medical injuries. Whether the topic is avoiding defensive medicine, encouraging self-critical analysis for the purpose of quality improvement, ensuring the availability of high (legal) risk medical services, or protecting the right of the injured, all eyes turn first to torts. Malpractice law and proposed reforms thereto are at center stage in the state and federal legislatures. In Japan, by contrast, although medical malpractice litigation is increasing, in the eyes of physicians and hospital administrators, civil damage actions are not of primary concern.

In American medicine, extra-judicial oversight activities carried out by entities such as internal hospital peer review committees, state licensure and discipline boards, Medicare Quality Improvement Organizations, and quasi-public accrediting organizations such as the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA) constitute key quality control mechanisms.

In Japan, by contrast, the analogous entities have traditionally been weak or dysfunctional. Peer review has been uncommon. Until recently, the nation's disciplinary board for physicians and dentists, the Medical Ethics Council (Id shingikai), has sanctioned practitioners only after a criminal conviction (typically for reimbursement fraud, morals violations, or drug abuse). Quality-of-care concerns have almost never formed the basis for administrative sanctions. The hospital accreditation entity analogous to JCAHO, the Japan Council for Quality Health Care (JCSHC, Nihon iryu kin by kaikai), operates on a far smaller scale and with a lower profile than JCAHO. This is due in large part to the fact that, unlike in the United States, Japanese hospitals need not be accredited to obtain payment for services rendered; the great majority have not undergone the JCSHC accreditation process—which, in any case, focuses chiefly on structure and process criteria, not on patient safety-related outcomes. Quality control has simply not been a significant aspect of the formal structure of Japanese health care.

However, there is a public accountability function that must be performed, at least in any society attentive to the rights and interests of individual citizens. Who offers assurance that the competence and the integrity of the professional class meet at least minimally acceptable standards? Who disciplines the profession's wayward members? In Japan, that public accountability function has been carried out in considerable part by the criminal justice system—police and prosecutors-amplified by the power of the media.

Consider the following events that took place at Aoto Hospital, a facility affiliated with Jikei Medical University in Tokyo. The story occupied column-meters of newspaper space and newscast top billing for a while in 2003.

[*1932]

In November 2002, three nephrology surgeons at Aoto Hospital, eager to gain experience with a high-tech procedure, obtained their supervisor's permission to perform a "keyhole" laparoscopy on a prostate cancer patient using sophisticated imaging equipment with which they were only slightly familiar. In obtaining the patient's consent, the lead surgeon, Dr. Jun Madarama, pitched the "keyhole" technique as promoting quick healing. He neglected mentioning his lack of experience at the procedure, the possibility of serious intra-abdominal bleeding experienced by patients of the university's other surgeons, or the existence of well-established standard alternative treatments. Neither Dr. Madarama nor his supervisor was required to clear either the consent materials or the proposed surgery itself with the medical school's ethics committee.

Reading from the equipment manual in the operating room, the surgeons consulted with the manufacturer's representative by phone as the operation proceeded. They persisted with the imaging equipment (giving them an indirect view of the operative field by TV monitor) despite nicking a vein, rather than falling back on standard surgical technique of opening the abdomen to afford a clearer direct view. Nine and a half hours into the surgery, the patient was bleeding heavily, but unfortunately the surgeons had also failed to procure an adequate supply of the patient's unusual AB blood type for transfusion purposes. An emergency transfusion could have been performed with Type O blood, likely available at the hospital, but neither the surgeons nor the anesthesiologist acted on this elementary fact. The patient went into shock, suffered renal and brain damage from lack of oxygen, and died a month later. Following the patient's death, the hospital director met with the patient's family and gave them a sanitized and misleading account of the circumstances of the operation.

Were this tragedy to have taken place in the United States, the young surgeon would have been subjected to a peer review process within the hospital, as would the anesthesiologist who failed to interrupt the course of events while the patient's blood pressure was dropping to dangerous levels. Suspensions of hospital privileges might have been in order, particularly if any of the physicians had exhibited a pattern of repeated sloppiness or lack of candor. Perhaps the supervising physician, who authorized the operation without requiring a more experienced surgeon to proctor it, might also have suffered some discipline. The incident would certainly have qualified as a "sentinel event" reportable to JCAHO, although whether in fact the hospital would have reported it is open to serious question. There is some chance that the patient's family might have filed a civil malpractice action-at most a one-in-three chance and probably much less, if the Harvard Medical Practice Study figures are to be believed. If a malpractice action were brought, the trial might merit mention in the local news.