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RECENT DEVELOPMENTS IN THE LAW OF PRODUCT LIABILITY IN JAPAN

TSUNEO MATSUMOTO

1. Introduction

In June 1994, the Product Liability Bill passed the Diet of Japan, and the new law became effective on July 1, 1995. The law is very simple, consisting of only six articles, and is roughly modeled on the European Community’s Council Directive on Product Liability. In this report, I will first briefly review the nature of product liability in Japan prior to the legislation, and then compare the provisions of the new law with those of the EC Directive.

The emergence of the concept of “product liability” in Japan can be traced back to the late 50’s and early 60’s. Japanese scholars specializing in Anglo-American law introduced to the Japanese readers the development and discussions of product liability in the United States. Although the Morinaga Milk case, which will be discussed below, happened as early as in 1955, scholars did not pay much attention to that case and did not take very seriously the problems arising from defective products. Rather, they discussed the product liability problem on a theoretical basis and proposed different ways in which to realize no-fault liability. Most of those scholarly opinions had their models in American, German, or French law.

In 1969, the news came from the United States that Japanese auto manufacturers had recalled automobiles manufactured in Japan and sold in the United States because of potentially injurious defects. Following this incident, the attitude of the public and scholars toward product-related injuries changed substantially. With the growth of the Japanese economy and the concurrent rise in the number of product-related injuries, consumers began to claim that manufacturers should accept responsibility and provide compensation for injuries due to defects in products.

In spite of the numerous injuries caused by defective products, there has only been a small number, roughly 200, of court decisions reported so far relating to product defects. Generally speaking, the courts have tended to decide these cases based on negligence principles, although, in serious toxic tort cases, the courts are known to occasionally impose a very high standard of duty of care, and in fact recognize no-fault liability.
2. **Mass Injury Cases**

Mass injury cases illustrate some of the characteristics of Japanese product liability law. Legal theories asserted by the plaintiffs' lawyers are similar to those developed in the large-scale environmental pollution cases, such as the Minamata Disease Case caused by mercury contamination.  

2.1. **The Morinaga Milk Case**

In 1955, almost 12,000 babies were injured and 131 died after consuming arsenic-contaminated powdered milk produced by Morinaga Milk Co., Ltd. A suit was filed in 1973 by a group of victims against Morinaga and the government of Japan. In April 1973, the parties agreed that a foundation (the "Hikari Association") would be established for the purpose of overseeing long-term relief work of the victims. Morinaga and the government announced in the trial proceedings that they would not contest the question of causation and that the beneficiaries of the Hikari Association would include any person subsequently identified as a victim. The suit was withdrawn shortly thereafter.

The Hikari Association started its work in April 1974 with funds provided by Morinaga. It is important to note that the Association did not compensate for death. In addition, the basic issues, such as Morinaga's negligence, government liability and the causal relationship between the product and the injuries were not addressed in the settlement agreement. As a result, a separate suit for the recovery of damages was filed by the parents of a deceased victim. The court rendered a judgment for the defendant, Morinaga, on the grounds of statute of limitation.

2.2. **The Thalidomide Case**

The second mass injury case is the Thalidomide case. In 1954, the Ministry of Health and Welfare permitted sleeping pills called "Isomin" containing Thalidomide to be manufactured and sold. Babies with deformities were born after 1960. The manufacturer stopped distributing the drug in May of 1962. They did not, however, admit that the drug was the cause of the abnormalities. Between 1963 and 1965, a total of 63 families brought action in eight different district courts against the drug manufacturer and the Japanese government.

Subsequently, in October 1974, the plaintiffs' group, the government and the drug manufacturer reached a settlement agreement. The parties signed a confirmation statement and a memorandum, and the defendants agreed upon the outline of a long-term annuity system for the victims. In the confirmation statement, the Ministry of Health and Welfare and the drug manufacturer admitted that Thalidomide had caused the deformities and that they were the parties responsible for the injuries. The compensation proposal called for an immediate

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3 For details of the major pollution cases, see J.Gresser, K.Fujikura and A.Morishima, ENVIRONMENTAL LAW IN JAPAN (Cambridge, 1981) p.55 ff.

4 Hagiwara v. Morinaga Milk, Co., Takamatsu High Court decision of February 13, 1985, Hanrei Jiho No. 1280, p.80.
lump-sum payment to the plaintiffs. Alternatively, the plaintiffs could also choose to receive a partial lump-sum payment and receive the balance as an annuity beginning three years after the settlement agreement. Furthermore, the same relief were to be given to those victims who did not join in the suit. Finally, the manufacturer promised to establish a Thalidomide welfare center to oversee the medical treatment, education and employment of the victims.

2.3. The SMON Case

The third example is the so-called SMON case. "SMON" is an acronym of Subacute Myelo-Optico-Neuropathy, a disorder of the nervous system. Plaintiffs alleged that SMON was caused by the use of drugs containing clioquinol. More than 5,000 plaintiffs brought action before 26 district courts throughout Japan, seeking damages totaling 110 billion yen. The defendants included Ciba-Geigy Japan, Ltd., Takeda Chemical Industries Ltd., Tanabe Seiyaku Co., Ltd., and the Japanese government.

In 1977, when the evidences submitted by the plaintiffs on the causal relationship between the disorder and the drug were becoming overwhelming, the defendant companies asked the Tokyo District Court to suggest a settlement proposal. In response thereto, the presiding judge proposed a special settlement procedure similar to an arbitration. Albeit reluctantly, 35 out of the 154 plaintiffs in the Tokyo District Court and 2 out of the 3 defendant companies accepted the proposal in October, 1977. The remaining parties continued to litigate.

Later, nine district courts rendered judgment for the plaintiffs and held the defendant manufacturers and distributors liable in tort, and the government liable under the State Compensation Law.

Although all of the defendants appealed, informal and non-judicial negotiations were started after the lower court judgments were rendered. In September, 1979, a note of confirmation was eventually signed by all parties. In that note, greater relief and remedies were provided to the victims than were given under the settlement proposal of the Tokyo District Court in 1977. And this confirmation note gave an impetus to the conclusion of settlement agreements in many courts soon thereafter.

It should be noted, however, that in the settlement agreements, those victims who were unable to identify which of the defendant manufacturers was the manufacturer of the clioquinol-containing drug they had been taking were excluded from the settlement. The theory of market share liability adopted in the famous DES case in California has not yet found support in Japan.

2.4 The Kanemi Rice Oil Case

The Kanemi Rice Oil Case is another example of a mass injury case. In 1968, more than 10,000 persons in 31 prefectures in western Japan suffered injuries from PCB (polychlorinated biphenyl) poisoning, and at least 142 people died. PCB poisoning causes loss of hair.

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5 Details of the negotiation process can be found in Diary of a Plaintiffs' Attorneys' Team in the Thalidomide Litigation, 8 LAW IN JAPAN 136 (1975).
6 The Translation of the Settlement Terms and Other SMON related materials are carried in 12 LAW IN JAPAN 99 (1979).
perception impairment, numbness of the limbs, pains in the joints, and severe skin inflammation, among other disorders. The poisoning was traced to a rice bran cooking oil produced by the defendant Kanemi Warehouse Company. The oil had been contaminated with PCB which was being produced and distributed by the co-defendant Kanegafuchi Chemical Industry Co., Ltd. PCB was used as a heating medium in the rice oil production process. It was discovered that the PCB had corroded the piping and found its way into the oil.

Until 1986, the lower court decisions held for the plaintiffs. Most of these decisions held both Kanemi Warehouse and Kanegafuchi Chemical liable, although they did not find the other co-defendant, the Japanese government, to be liable. Kanemi Warehouse did not even appeal. However, an appellate court decision in 1986, finding no liability on the part of Kanegafuchi Chemical and the government, started to change the whole atmosphere. In 1987, when the case was in the Supreme Court, Kanegafuchi Chemical and the plaintiffs signed a court-supervised settlement. In that settlement, Kanegafuchi Chemical was not held liable, but the company promised to pay on the average 3,000,000 yen per plaintiff. The liability of the government was not made clear in the settlement agreement. Shortly after the settlement, all the other suits were withdrawn.

2.5. Out-of-court Settlements

The foregoing examples suggest that judicial remedies are, by their very nature, of limited use. Dispute settlement through negotiation, on the other hand, has proven to be effective. Some settlement agreements, as in the Morinaga Milk Case, provided for establishing a fund to handle the health care, educational and employment problems of the victims. That solution was more effective than a mere lump-sum payment of damages as compensation for the injuries.

However, such settlement agreements were not reached until the victims have had recourse to judicial remedies and filed suits against the manufacturers and the government. It would be fair to point out, generally speaking, that the effectiveness of settling disputes of this nature through negotiation is often preconditioned on the filing of a law suit, or even on the court’s rendering a final judgment in favor of the plaintiff.

Mass injury cases caused by defective food or drugs always attract public attention nation-wide and have a good chance of being settled one way or another. The government will try informally to mediate the negotiation between the injured and the manufacturer. In contrast to those mass injury cases, an isolated case, for example, in which one baby allegedly suffocates in an overly elastic bed, the defendant will typically deny the existence of a defect in the product and will rarely agree to a settlement.

3. Limited Scope of Japanese Law of Product Liability

I would now like to turn to some other aspects of the law of product liability in Japan. The relative small number of private litigation in Japan is often ascribed to the Japanese antipathy towards litigation. In product liability cases, there are other reasons which should be mentioned. The area covered by the law of product liability is definitely smaller than in other industrialized countries. The scope of product liability is also limited by several government-
supported compensation systems, although these only cover injuries caused by certain kinds of products or situations. These systems help reduce the number of product liability litigation.

3.1. The Compulsory Automobile Accident Liability Insurance System

The most important of the compensation systems is the compulsory automobile accident liability insurance system. Article 3 of the Automobile Injuries Indemnification Guarantee Law provides that when a person, who places an automobile in the use of operation for his own account, causes damage to the life or body of another person by such operation, he is obliged to compensate for the resulting damage. The automobile operator will be exempt from liability if he proves all three of the following facts. He must first prove that he did not act negligently in the operation of the automobile; secondly, that there was an intention to be injured or negligence on the part of the injured party or a third party other than the actual driver; and thirdly, that there was no structural defect or functional disorder on the part of the automobile.

Article 3 of the Law, with the three specified exceptions, is interpreted as establishing a no-fault liability system. The third item to be proven for being exempt from liability is particularly noteworthy in the context of product liability. Proof of non-existence of defects will relieve the automobile operator from his liability under Article 3 if the other two requirements are met. In other words, the assumption of liability for defects in an automobile rests, first of all, on its operator (who is often its owner). An operator, therefore, assume a form of substitute liability, and claims against manufacturers for indemnity may most likely be made by the operator-defendant, though such cases have rarely been reported. The nationwide compulsory liability insurance system, combined with the quasi-no-fault liability principle, therefore, serves to limit the scope of the operative area of the product liability doctrine.

3.2. The Workers' Compensation System

The second example of special legislation which reduces the necessity for product liability litigation is Workers' Compensation Insurance Law. Workers who are injured at the work place may receive compensation from the state-run insurance, even if the employer's fault is not proved, or defective equipments or machines caused the injury. An employee may hold his employer liable for that portion of the damages not compensated for by the insurance provided for under the Law, if he can prove contractual liability or general tort liability. Theoretically, in the case where a defective machine was involved, the employer and the manufacturer of the machine may be liable jointly and severally. However, employees tend to sue employers only.

3.3. Compensation System under the Consumer Product Safety Law

The Consumer Product Safety Law was enacted in 1973. This law provides not only for safety standards, an approval system of an entire model type of products, and other administrative procedures, but also establishes the Association for Product Safety and authorizes the said Association to manage an insurance-based compensation program. If a product meets the safety standards, the Association allows an “S.G.” mark (which stands for “Safety Goods”) to
be placed on the product, charging a small cost to the manufacturer per mark. The Association takes out product liability insurance policies on a group-basis for all of those products. Premiums are paid from the proceeds of the S.G. mark.

When death or physical injury occurs because of a product under the program, the Association will pay compensation up to a maximum amount of 30 million yen per person. The compensation, however, is paid only when it is determined that negligence of the injured party was not the cause of the accident and that the manufacturer is “legally” responsible for the injury. This requirement diminishes the benefit of this compensation system as an alternative to litigation, because as a result, the Association and insurance companies are compelled to make quasi-judicial determinations of the facts in the course of their settlement negotiations with the injured party.

3.4. Compensation System under the Drug Side Effects Injuries Relief Fund Law

Another example of the government-supported compensation systems is the system under the Drug Side Effects Injuries Relief Fund Law of 1978. The Law established a relief fund out of which compensation is paid to victims or survivors for illnesses, disabilities or deaths caused by drug side effects. The victims do not need to prove negligence on the part of the drug manufacturer, or even defects in the drug. On the contrary, if the manufacturer's negligence is clear and the victim is able to prevail in a suit against the manufacturer, the victim is barred from seeking compensation from the relief fund.

To source the funding, the relief fund collects a charge from the pharmaceutical companies. The charge consists of two parts: a general charge and a causative charge. The first one, the general charge is contributed by all the drug manufacturers and importers proportionate to the volume of their drug sales. The second one, the causative charge, is paid in addition to the general charge by those manufacturers and importers whose drugs have caused injuries resulting in compensation being borne by the relief fund.

Because there are these two different kinds of charges, the exact legal nature of such relief payment is not simple. With respect to the causative charge, it can probably be characterized as a special no-fault type of product liability. However, the imposition of the general charge on those manufacturers and importers who have nothing to do with the injuries is not based on any direct liability, but can be seen as an industry-wide sharing of liability.

3.5. Compensation System of Victims of Side Effects of Blood Products

Side effects caused by blood products are excluded from coverage under the foregoing compensation system, because of the possibility of blood products containing unknown viruses. Unfortunately, the number of hemophiliacs reported being infected with the AIDS virus after taking blood plasma products processed from blood collected in the United States is increasing. In answer to the demands of these victims, the Ministry of Health and Welfare started in 1989 a new compensation system similar to that for drug side effects injuries. Seven manufacturers of blood plasma products for treating hemophiliacs and other drug manufacturers contribute to the fund. Only those who are symptomatic of AIDS may receive compensation, and those who are HIV infected but not yet symptomatic may not. This limitation caused many victims to file suit against the manufacturers and the government in the
Tokyo and Osaka District Courts.

In October 1995, the presiding judges of the Tokyo and Osaka District Courts proposed a settlement plan to the plaintiffs and the defendants. The lump-sum payment in the proposal amounts to 45 million yen per victim.

4. The New Legislation

4.1. Proposal of the Legislation

In 1975, a group of leading civil law professors proposed a draft for a no-fault product liability law. The content of the draft was strongly pro-consumer. Because at the time there were several serious cases pending in the courts, including the above-mentioned cases, the government neglected to put an effort into drafting a new law, and neither did the professors lobby hard to have their proposal considered for legislation. For them, their proposal was an academic exercise.

During the 70's and 80's, the law of product liability was developed by court decisions and scholarly articles commenting on those decisions. The issuance of the EC Directive on Product Liability in 1985 and the implementation of the Directive by the member states again aroused interest in product liability legislation in Japan. In 1989 and through 1990, two opposing political parties, the Japan Federation of Bar Associations, Tokyo Bar Association, and another group of civil law scholars including myself, belonging to a younger generation of scholars than those who made the proposal in 1975, made public the outline of their respective drafts.

Common to all of these proposals, the defense of "development risk" was not allowed, and they all contained provisions regarding certain "presumption of facts," such as the presumption of defects or presumption of causation, or both. Looking at their texts, these drafts were more protective of the injured consumers than the EC Directive.

4.2. Opposition to Legislation

In December 1990, the Consumer Policy Section of the Social Policy Council, an advisory organ reporting to the Prime Minister, began discussions on preventive measures of and comprehensive relief from injuries to consumers. From the outset, it was expected that the Council would propose legislation of product liability similar to the EC Directive. However, contrary to such expectations, a report published in October 1992 by the Consumer Policy Section after two years of deliberations was a disappointing one for the consumers. While the report did not clearly oppose such legislation, it reflected a noncommittal attitude of the Council.

The then incumbent Liberal Democratic Party's Sub-Committee on Product Liability had

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8 See T. Kishimoto, Product Liability for Drugs through HIV Case from Blood Product, in GLOBAL TRENDS OF CONSUMER LAWS IN A CHANGING WORLD 199 (Papers from The JAPAN SEMINAR ON CONSUMER AFFAIRS 2-4 AUGUST 1994, published by the College of Law, Ritsumeikan University 1995).
made public its own negative view, which reflected the business sector's vigorous opposition to such legislation of no-fault liability.

The opponents joined in citing the experience in the United States as one of the reasons for their opposition. They said that the law of product liability as developed in the United States which is too generous to the consumers raised the premium of liability insurance, making insurance unaffordable and unavailable, that product liability has resulted in U.S. industries being less competitive in the world market, and that Japan should not make the same mistake. I do not believe such reasoning is correct.

4.3. No Tort Crisis in Japan

In Japan, we do not have a "tort crisis" or insurance crisis as can be found in the United States. The number of civil cases filed in the district courts in Japan is decreasing gradually from about 220,000 in 1980 to 190,000 in 1990. The insurance companies in Japan are not losing money by providing liability insurance.

Why, then, do we not suffer from explosively numerous litigation and a tort crisis in Japan? In the past, the theory put forth by Professor Kawashima of Tokyo University was widely supported. He wrote in 1967 that the rights-consciousness of the Japanese people was still underdeveloped and that the pre-modern society still in existence in Japan made the Japanese less litigious. Now, quite a different theory is being proposed, and is gaining support. The advocates of the new theory assert that the relative non-litigiousness of the Japanese has nothing to do with underdeveloped rights-consciousness. They say that ADR has been working relatively well in Japan and that litigation is not the only and best one.

I cannot throw my full support to this claim. ADR would not work very well if the rule which the judges would apply in that case pending before the court. I guess the relatively small incidence of litigation in Japan might be explained, if we look into several institutional factors which would discourage the injured having willingness to file a suit in Japan.

The first factor is that it is relatively difficult to bring a civil suit in a Japanese court. The plaintiff must have ready a substantial amount of money before initiating a suit. As a rule, a client, upon retaining an attorney, is required to pay up front a lump-sum retainer fee. There is a standard schedule of attorney's fees set by the Japan Federation of Bar Associations based on the amount in controversy, but many attorneys are willing to offer their services for less than the fee stipulated by the schedule. If the damages being sought is, for example, $1 million, the up-front retainer fee according to the schedule will be $45,000. If the plaintiff is awarded the damages sought, he will be required to pay his attorney a success fee in an amount equal to the up-front retainer fee. In addition, there is a court filing fee to initiate the suit, also calibrated to the amount in controversy — using the same example, the filing fee will be $5,000. Just to initiate the lawsuit in the foregoing example seeking $1 million in damages, one would need to have ready up front a total of $50,000 for the court filing fee and the up-front retainer fee for the attorney. It would obviously present a serious obstacle if the injured party is indigent. It should be added that a pure contingent fee arrangement is considered to be

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against public policy and is therefore unenforceable under Japanese law.

The second institutional factor is that, even if the plaintiff manages to file a suit, it is not easy for him to win the case. Because there is no extensive discovery procedure under Japanese civil procedure as there is in the United States, the plaintiff faces a very serious problem of gathering the evidence needed to support his case. I consider this to be a significant factor in there being such a small number of product liability cases in Japan. And in Japanese civil cases, a high degree of probability is required in proving a fact, a much higher threshold than the Anglo-American standard of preponderance of evidence. Furthermore, the jury system, which often greatly favors the injured party in the courts in the United States, is non-existent in civil proceedings in Japan.

The third institutional factor is that the amount of damages awarded in a judgment tends to be small. There is yet another standard schedule, in this instance, of damages which should be awarded for personal injury, which was developed over the years jointly by judges, attorneys and insurance companies based on automobile accident cases. Before the Automobile Injuries Indemnification Guarantee Law was enacted in 1955, a considerable number of lawsuits had been filed in the courts and a fair number of court decisions had been reported. At that time, automobile accident cases were a major source of income for a practicing attorney. After the legislation, the greater part of automobile accidents are handled by employees of insurance companies without the intervention of attorneys.

The fourth factor may be that it is hardly possible for Japanese attorneys to make big money on a lawsuit because plaintiffs’ attorneys cannot have a pure contingent fee arrangement and defendants’ attorneys ordinarily do not charge their clients based on the amount of time they spend defending their clients.

4.4. The L-Tryptophane Case

Showa, a Japanese chemical products manufacturer, exported to the United States L-Tryptophane, an essential amino acid, which was an ingredient of a type of nutritional supplement product. In the manufacturing process, Showa’s L-tryptophane was contaminated with impurities injurious to health. In a short period of time, approximately 1,500 victims were reported in the United States, and more than 1,000 lawsuits were filed. During their fiscal year 1991, it is estimated that Showa paid out about $66 million in settlement with the injured in the United States, although Showa would not make public the exact settlement figures. Showa also paid over $100 million in litigation and settlement costs, most of which I believe was attorneys’ fees. Showa’s losses were to be much greater in the following fiscal year.

In Japan on the other side of the Pacific, the exact number of the victims of contaminated L-Tryptophane is still unclear. In 1992, a newspaper reported that a 52-year old housewife was going to institute a lawsuit, but she has not done so yet. Her attorney told me that she still lacks sufficient evidence which can be admitted in a Japanese court.

What, then, could possibly account for the marked differences in the development of the law of product liability in the United States and Japan? Even after we introduced the strict product liability rule into our legal system, we have not gone the way the U.S. has gone. I would say what accounts for the differences is the difference in the respective civil procedure system implementing tort claims, and not the substantive tort doctrine.
4.5. Legislation, at Last

In December 1993, after three years of intensive nation-wide debate, the Consumer Policy Section of the Social Policy Council finally conceded in concluding that a no-fault product liability legislation should be introduced. What brought about the concession, then? I would like to propose three factors.


b. A change in the political situation. After the general elections held in the summer of 1993, the Liberal Democratic Party which had ruled Japan since 1955 fell from power. A coalition of the former opposition parties except the Communist Party took over the administration. The new government showed more concern for the interest of consumers.

c. A cry for deregulation from outside Japan, that is, the United States and the European Community.


5.1 Elements of the new Product Liability Law

"Product" is defined in Article 2, Paragraph 1, as "movable property manufactured or processed." Immovable property (which includes not only land but also buildings and other structures thereon) is excluded; construction materials, however, would come under the definition, and injuries resulting from defective construction materials, for example, would be covered. Primary agricultural products are excluded from coverage.

The party liable, referred to as "manufacturer, etc." is defined in Article 2, Paragraph 3, so as to include not only the actual manufacturer/processor or importer, but also any person who, by virtue of labeling, etc., represents himself to be the manufacturer, or may be recognized as the manufacturer-in-fact. This broadening of the scope of the liable party is not found in the EC Directive.

The provision of manufacturer-in-fact is rather complicated, and is best illustrated by an example. Labeling on canned soft drinks sold in Japan most often identify only the distributor or seller, and rarely bear a representation as to who the actual manufacturer is. With the provision of Article 2, Paragraph 3, Item 3, which identifies "any person who, by putting the representation of name, etc. on the product may be recognized as its manufacturer-in-fact ..." also as "manufacturer, etc.,” these soft drink distributors, in the absence of identification of the actual manufacturer, are deemed to be the manufacturer of the product and thus will have product liability exposure.

Defect in a product is defined in Article 2, Paragraph 2, as the "lack of safety that the product ordinarily should provide, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, and other circumstances concerning the product." In order for there to be liability, the defect must have existed at the time the product was delivered, that is put into commerce, by the manufacturer, etc., and the burden of proof
thereof must be borne by the injured party.

Under the Law, there is no minimum or maximum limitation placed on the amount of damages to be compensated, other than to exempt the manufacturer, etc. from liability when the only damage is that of the defective product itself with no other injuries suffered. In all other cases, the provisions of the Civil Code shall apply, and any and all damages for which appropriate causal relationship can be found will be compensable.

Furthermore, the Law does not limit the "damage to property" to damage to an item of property for private use or consumption, as does the EC Directive. Article 1 of the new Japanese Law states that the purpose of the law is to "relieve the injured person," without limiting "person" to natural persons. This means that under the new Japanese law, not only injured natural persons, but also injured juridical persons may seek damages for their economic loss including lost profit. From a pure consumer protection point of view, one may say that the Law is overzealous in that it affords relief not only to consumers but also to businesses. One very real concern that arises is, should case law develop in such a manner so as the courts begin to deem the amount of relief being awarded to businesses to be excessive and start curtailing the damages awarded, the curtailing effect may spill over to injured consumers as well.

Manufacturer, etc. will be exempt from liability if either of the following can be shown (Article 4):

1. that the state of scientific or technical knowledge at the time when the manufacturer, etc. delivered the product was not such as to enable the existence of the defect in the product to be discovered (the so-called "development risk"); or
2. in the case where the product is used as a component or raw material of another product, that the defect is substantially attributable to compliance with the instruction concerning the specifications given by the manufacturer of the said another product, and that the manufacturer of the component or raw materials is not negligent on occurrence of the defect of the said another product.

Extinction of rights by prescription is set at 3 years from the time the injured party becomes aware of the injury and the liable party for the damage; and 10 years from the time the manufacturer, etc. delivers the product. However, the 10 year period will be calculated from the time when the damage arises for a damage caused by substances injurious to human health whose effects appear after a certain dormant period. This latter feature, not found in the EC Directive, is a manifestation of the lesson learned through the SMON and other drug-related mass injury cases.

5.2 Comparison with the EC Directive

As I stated before, our new Product Liability Law is modeled on the EC Directive. With regard to the three options from which EC member states are permitted to deviate, Japan followed the way the majority of the member states went, namely:

a. Development risk is included as a defense for exemption from liability.
b. Primary agricultural products are excluded from coverage.
c. No maximum limitation is set on the amount of damages to be awarded.
There are three divergent aspects in the new Japanese law that are less favorable to the consumer relative to the EC Directive, as follows:

a. Japanese consumers must prove that the defect in question existed at the time the product was put into commerce.
b. The issue of presentation of a product is conspicuously absent in the language of article 2, which lists the factors to be taken into consideration when a judge decides whether or not the product was defective; the issue of presentation of a product should be included in "other circumstances concerning the product."
c. There is no rule under Japanese law which gives rise to a deemed liability when the supplier of a defective product is unable to identify the party from which the supplier received the defective product.

There are four aspects more favorable to the consumer than in the EC Directive:

a. Distributor's liability is provided for in a certain type of labeling.
b. For certain types of chemical and pharmaceutical products, the ten-year prescription period begins to run later when symptoms of the injury first appear.
c. Damage to the defective product itself may be recoverable, provided that it is not the sole damage caused by the defective product.
d. There is no limitation as to the amount of damages that can be awarded.

6. Conclusion

With the new Law, the operative principle of product liability in Japan has changed from one that was based on negligence to one that is based on strict liability. But the new Law provides no concrete measures to ease the consumers' burden of proving the existence of a defect, and the cause of the injury being attributable to the defect. These are still issues left for the judges to decide.

The manufacturers generally denied the existence of the alleged defect and the causation of the defect and the injury. Before the new Law was put into force, there had been few defendant manufacturers who raised the issue of negligence once after they agreed that the defect of their products caused the injury. The only exception are those in cases of defective pharmaceutical products. In sum, the Product Liability Law is merely an ex post factor ratification of what is already there, and there is no change from a statutory point of view other than the system being stabilized. But credit must be given to certain significant effects resulting from the nation-wide legislative discussions spanning several years.

The first of these effects is a societal consensus being formed, placing a high premium on product safety. That is to say, there is now an awareness of safety of products on the part of consumers (formation of consumer expectations), and on the part of the industries, the sense of securing product safety has been heightened (change in the awareness of top level management, greater on-site care, revision of user's manuals and warning notices).

The second effect can be seen in the increase of number of product related accident cases being settled after the Product Liability Law was enacted. This is probably an indication of change in the awareness and attitude on the part of the industries.
The third effect is found in the judges now being aware of the need to take into consideration the special nature of injuries to consumers. This point was well illustrated in the court decision of the television set combustion case\textsuperscript{11} rendered just before the cabinet submitted to the Diet its draft of the Product Liability Law. In that decision, the manufacturer was found to be liable pursuant to article 709 of the Civil Code upon the court's eagerly deducing on the issues of defect, causal relationship and negligence.

**APPENDIX**

The Product Liability Law (Law No. 85, 1994) (tentative translation)

Article 1 [Purpose]

The Purpose of this Law is to relieve the injured person by setting forth liability of the manufacturer, etc. for damages when the injury on a life, a body, or property is caused by a defect in the product, and thereby to contribute to the stabilization and improvement of the people's life and to the sound development of the national economy.

Article 2 [Definitions]

(1) As used in this Law, the term "product" means movable property manufactured or processed.

(2) As used in this Law, the term "defect" means lack of safety that the product ordinarily should provide, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, the time when the manufacturer, etc. delivered the product, and other circumstances concerning the product.

(3) As used in this Law, the term "manufacturer, etc." means any one of the following:

1. any person who manufactured, processed, or imported the product as business (hereinafter called just "manufacturer");

2. any person who, by putting his name, trade mark or other feature (hereinafter called "representation of the name, etc."), etc. on the product presents himself as its manufacturer, or any person who puts the representation of name, etc. on the product in a manner mistakable for the manufacturer;

3. apart from any person mentioned in the preceding subsections, any person who, by putting the representation of name, etc. on the product, may be recognized as its manufacturer-in-fact, in the light of a manner concerning manufacturing, processing or sales, and other circumstances.

Article 3 [Product Liability]
The manufacturer, etc. shall be liable for damages caused by the injury, when he injured someone's life, body or property by the defect in his delivered product which he manufactured, processed, imported or put the representation of name, etc. as described in subsection 2 or 3 of section 3 of Article 2 on. However, the manufacturer, etc. is not liable when only the defective product itself is damaged.

Article 4 [Exemptions]
In cased where Article 3 applies, the manufacturer, etc. shall not be liable as a result of Article 3 if he proves;

1. that the state of scientific or technical knowledge at the time when the manufacturer, etc. delivered the product was not such as to enable the existence of the defect in the product to be discovered; or
2. in the case where the product is used as a component or raw material of another product, that the defect is substantially attributable to compliance with the instruction concerning the specifications given by the manufacturer of the said another product, and that the manufacturer, etc. is not negligent on occurrence of the defect.

Article 5 [Time Limitation]
(1) The right for damages provided in Article 3 shall be extinguished by prescription if the injured person or his legal representative does not exercise such right within three years from the time when he becomes aware of the damage and the liable party for the damage. The same shall also apply upon the expiry of a period of ten years from the time the manufacturer, etc. delivered the product.
(2) The period in the latter sentence of section 1 of this Article shall be calculated from the time when the damage arises, where such damage is caused by the substance which are harmful to human health when they remain or accumulate in the body, or where the symptoms for such damage appear after a certain latent period.

Article 6 [Application of Civil Code]
In so far as this Law does not provide otherwise, the liability of the manufacturer, etc. for damages caused by a defect in the product shall be subject to the provisions of the Civil Code (Law No.89, 1896).