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# THE LIABILITY OF DRUGS—ANALYSES FROM THE STORY OF INTRAVENOUS IODINE-CONTAINED CONTRAST MEDIUM

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## I. THE CLINICAL USE OF IODINE-CONTAINED CONTRAST MEDIUM

### The Clinical Cases:

#### Case One:

Jin-Hua Cheng, 30 years old, male:

The patient is a generally healthy young male without previous history of any major disease. He visited our OPD department because he felt right flank pain in the past one month. After urine examination and abdominal sonography, the patient was diagnosed of kidney stone, bright side. He was transferred to radiographic department to receive IVP for further evaluation. No sooner had the radiologist, Dr. Lin, injected 10 c.c. of contrast medium, than the patient complained of sweating, blurred vision, and difficulty in breathing. Dr. Lin stopped I.V. injection immediately and began to give the patient emergent treatment. Oxygen, I.V. fluid, and Dexamethasone was given. But the patient developed to anaphylatic shock quickly. Dr. Lin decided to perform endotracheal intubtion to sustain the patient's respiration, but due to severe laryngeal edema, he failed again and again. Finally, he succeeded, but it was 10 minutes later. The patient had lost his consciousness, and E.K.G. showed arrhythmia and then, cardiac arrest. . .

Half an hour later, the patient was saved from death after CPR. He was transferred to I.C.U. for intensive care. Unfortunately, one week later, the patient died of pneumonia.

#### Case Two:

Ku-Tai Yang, 38 years old, male:

The patient is a victim of chronic hepatitis B. Five years ago, in a regular follow-up, sonography revealed a 2 x 2 cm hypoechoic lesion in his liver. He was transferred to radiographic department and received CT scans with contrast medium study and angiography (a vascular diagnostic procedure with injection of contrast medium under X-ray). Early hepatocellular carcinoma was diagnosed. Due to the early diagnosis, the malignant tumor was resected by surgery successfully. Now, the patient has been closely followed up in OPD, and no evidence of recurrence has been noted

#### Case Three:

Yi-Lu Liu: 21 years old, female:

The patient complained of fever, abdominal pain, and general malaise for three days. In the history-taking, she told the physician that she ate some sashimi several times during the past two weeks. Under the

impression of liver abscess, she was transferred to radiographic department for further evaluation. The CT scans with contrast medium study reveals a round hepatic lesion with central necrosis and peripheral contrast medium enhancement. Liver abscess due to ameba was diagnosed. After hepatic puncture and drainage, the patient was totally cured.

## **The Intravenous Injected Contrast Medium—The Dilemma to Radiologists, Patients, and Administrative Agency**

### **A. The Double Faces of Intravenous Contrast Medium—A Basic and Useful Diagnostic Tool and A Nightmare for Doctors and Patients**

Iodine-contained contrast medium is a very useful tool for doctors. It is a liquid compound with radio-opaque characteristic under X-ray. With intravenous injection of contrast medium in different kinds of X-ray examinations, doctors can get medical imagines with more sharpness and clarity. Because many lesions like tumor or inflammation lesions have abundant and characteristic blood vessels, doctors can get much diagnostic information by comparing with medical imagines before and after the administration of intravenous contrast medium. Without the help of contrast medium, it would be impossible for doctors to accurately make diagnoses. It is relatively safe, quickly excreted through kidney, and not accumulated in human body. Except for this kind of iodine-contained contrast medium, no other chemical compound can be found in the market with characteristics like iodine-contained contrast medium and without toxicity at the same time.

But iodine-contained contrast medium has some unavoidable adverse reactions. Some patient will develop allergic reactions to it. Under intravenous administration, it can cause whole body symptoms quickly. Some mild allergic reactions, like skin rashes (urticaria), temporary hypotension, tachycardia, and angioedema are quite common. These mild allergic reactions can be treated easily, and no residual damages will exist. But in some instances, severe reactions will happen—like laryngeal edema, anaphylatic shock, and even death. For those patients who never accepted contrast medium before, it is impossible to predict whether they will suffer from which kinds of adverse reactions. For other patients having previous allergic reactions to this drug, it is a contra-indication to use this drug again, because the immune system will response to this drug more vigorously. In other words, the immune system has memory against this drug. Some patients do lead to anaphylatic shock just by receiving 1 c.c. contrast medium at the first time. Some patients die of these severe reactions, although they are generally healthy and just receive very little amount of intravenous contrast medium due to the diagnostic goal of a small kidney stone. So, these severe hypersensitivity reactions have become the nightmare of radiologists, and of course, the patients.

### **B. The Dilemma of Clinical Use of Contrast Medium**

Among the numerous drugs widely used clinically, iodine contained contrast medium is a very special and controversial one. It is a drug used in the diagnosis of diseases instead of treatment of diseases. For most drugs, treatment of diseases is their goals. Although there are many side effects and adverse reactions, patients are more easily to accept them. They are willing to suffer from these side effects or adverse reactions,

if these drugs can cure their diseases. For those patients, they receive less severe detriment in order to get rid of more severe diseases. It is quite a worthy deal. On the contrary, iodine-contained contrast medium is a diagnostic drug. Many patients who receive injection of contrast medium are generally healthy or just have minor diseases. If they become seriously ill or even died by using intravenous contrast medium, they or their families would not accept the results totally.

Minor allergic reactions caused by intravenous contrast medium are quite common, such as skin rashes, itching, nausea, and vomiting. Some patients would suffer from angioedema, temporary hypotension, and tachycardia. Those adverse reactions are not life-threatening. Only very few patients can response to this drug vigorously, and develop to anaphylatic shock or death. On the other hand, It is a necessary and very useful diagnostic drug in radiology. Without intravenous contrast medium, accurate diagnosis is impossible in many circumstances. Numerous patients benefit from it to make an accurate diagnosis and to receive accurate treatments. Although this drug has adverse reactions, it seems acceptable to take some reasonable risks to get its benefits.

These facts lead to a dilemma for decision-makers. For patients, they are concerned about whether the drug is safe or not. If they encounter with adverse reactions, who will cover their damages, i.e. who should take the responsibility? The doctor, the pharmaceutical company, the distributor, or administrative agency? What are their legal rights? For doctors, they are concerned about if they don't have any negligence in medical practice, should they cover the unfortunate damages of patients? What is the relationship between medical malpractice and negligence? Is there any duty for doctors to inform patients before using this drug? For administrative agency—in Taiwan, it is Department of Health (DOH)—the commissioners are concerned about whether they should allow this drug in clinical use. Should they prohibit some brands of contrast medium due to higher incidences of adverse reactions, even though those brands are cheaper? What is the balance between cost and benefit in consideration with the budget of National Health Insurance Program (note 1)?

All the concerns about intravenous iodine-contained contrast medium are important, but difficult to judge quickly and even controversial in some circumstances. It is necessary to take many factors into consideration, including the legal theory, the medical science, the administrative regulation, and the public thoughts. It is really a challenge to researchers

## II.

### A.

#### 1.

As a civil law country, Taiwan's contract law follows a strict principle originating for the time of Rome—*alteri stinulari nemo potest—the relativity of contract*. It means that the liability of contract exists only between the parties of contract, and no body can make any contract for anyone without his admission. In the cases of damages caused by intravenous contrast medium, the patients go to hospital to receive the radiological examination. They have a contract with the hospital, or with the doctor performing the procedure. There is no contractual relationship between the patient and the pharmaceutical company. So based on contract, the pharmaceutical company has no liability to cover the damages of the patient. Even though the producers are the most powerful economic entity to cover the damages of the consumer—the patient. The patient can sue the hospital for damages based on the contract. In fact, it is a time-consuming process, if the patient take civil procedure based on contract. The possibility for the patient to win is quite low, because the patient need to prove that the hospital has violated the contract. The burden of evidence is quite detrimental to the plaintiffs.

## 2.

In the cases of the early days, courts' decisions were still based on contractual relationship. Because there is no contractual relationship between the patients and the producer, and the producer has no negligence in the production of the drug, the patients have few chances to win the litigation based on contract. In 1960, in *Gottsdanker v. Cutter Labs* (note 2), the court overcame the limitation of contract, and insisted that the producer should have the liability of implied warranty. In *Hennigsen v. Bloomfield Motors, Inc.*(note 3), Judge Francis delivered the opinion that even though there is no direct contract between car producer and consumers, consumer can sue producer based on implied warranty of merchantable goods. After these cases, the courts constructed the legal rights for consumers to sue directly against producers even though there is no direct contract between them.

About implied warranty, U.C.C.2-318 reveals the rule of third party beneficiary of warranties expressed or implied. This is an important statute about the liability of producer.

Can the patients damaged by contrast medium insert the implied warranty of this drug? Adverse reactions of contrast medium have been well understood by producers, and they belong to unavoidable scientific limitation (note 4). Those patients have idiosyncratic or hypersensitive characteristics are more vulnerable to adverse reactions of contrast medium. In the package insertion of contrast medium, medical textbooks, and agreement for patient to sign before radiographic examination all reveals these facts. The producers can reasonably and successfully defend by waiver of warranty. It seems that the patients still can not recover from producers by inserting implied warranty.

## B.

## 1. The view of Taiwan

According to the Civil Code # 184, the liability of tort is based on subjective intention or objective negligence of the defendant. The other criteria are 1) the conduct of action, 2) invasion to other's legal rights, 3) the result of damage of legal rights, 4) the cause-to-result relationship of action and damage. It is clear that the defendant can insert that there is scientific limitation in the development of safer contrast medium, and no negligence in the producing process of contrast medium. Every brand of contrast medium in the market shares the same adverse reactions. Some pharmaceutical companies do develop non-ionic, hydrophilic contrast medium to reduce the possibility of adverse reactions, but they just can reduce the incidence, rather than totally eliminate them. Those safer new products are also iodine-contained, but more expensive.

Like any other drug, contrast medium has reasonable risks to consumers. No drug in the world has no side effect or adverse reaction. If the pharmaceutical company has revealed this information to the consumer, and the consumer accepts the reasonable risks, there is no basis for claiming tort to the company. Unless there are technical negligence in the producing process or misbranding of the product, the producer has no liability based on tort. At the same time, the burden of evidence to prove negligence in the manufacturing procedure or misbranding is on the shoulder of the plaintiff. It is easy to imagine how difficult for an ordinary consumer to prove the manufacturing negligence of a big pharmaceutical company. Based on traditional theory of tort, the patient can recover nothing from producers.

## 2.

### a.

In the early days of product liability cases in America, for the claim based on tort, the plaintiff should have contractual relationship with the defendant, and the plaintiff should also take the burden of evidence. The first step toward strict liability of product was *MacPherson v. Buick* (note 5). The court's decision established the principle that a manufacturer has a duty to take care a person who is not the customer who bought the product for him. It was the first time the plaintiff could overcome the restriction of contractual relationship. So far, the plaintiff still had to prove the negligence of the producer. The turning point was *Greenman v. Yuba Power Products*. Reliance on negligence or on breach of warranty was no longer necessary, and the victim of a defective product could just insert his claim based on strict liability in tort. The liability exists when the manufacturer knew that the product would be used without inspection. The court's decision

was adopted by the American Law Institute, which was working on a new edition of its Restatement of the Law of Torts. It became the famous Section 402 A:

Special Liability of Seller of product for Physical Harm to User or Consumer

(1)

(a)

(b)

(2) The rule stated in subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user and consumer has not bought the product from or entered into any contractual

relation with the seller.

Should strict liability of products apply to drugs? Because all drugs exist unavoidable side effects or adverse reactions, applying strict liability to drug without limitation may be to extreme to producers. It will lead to huge cost of R&D and insurance expense. The time for a new drug development will greatly prolong. The prices of drugs will be very high, and consumers are unable to afford any new drugs.

Comments of Section 402 A seems to provide pharmaceutical producers with defenses. Nevertheless, many authors argued the reasonableness of that clause. In other words, if every producer can use that defense, how to find the remedy for a consumer's damage? In many cases, like Thalidomide and DES, the harm caused by them is tremendous, and the judicial decision is closely associated with social policy. These cases are really difficult. In *Smith v. ER Squibb & Sons* (note 6), the patient died of anaphylatic shock after intravenous injection of Renograffin-60. The product is a purified one and no evidence of negligence in the manufacturing process. The cause of death is not the defect of Renograffin-60, but the idiosyncratic characteristic of the patient. The court inserted that even though the drug, Renograffin-60, is a product of purified one, the producer should take the strict liability of product because of lack of a clear and necessary warning. In *Sindell v. Abbott Laboratories* (note 7), the plaintiff is a victim of DES. Her mother took DES when she was with her. The plaintiff then developed rare vaginal cancer in her childhood due to the side effects of DES. Because the process is quite long, the plaintiff could prove which producer did manufacture the drug taken by her mother. The dilemma here is if the plaintiff couldn't prove the defect of certain producer, the law of

torts will be reluctant to cover the damage of the plaintiff. The court, on the ground of public policy, gave the verdict to the plaintiff, based on established principles that compensation for the harm would come from some at least of those who had profited from the product in the past.

Does strict liability of product apply to contrast medium? According to Restatement of Tort, Section 402 A, Comment (k), most authors think drug is exempted from strict liability if the manufacturer can qualified some requirements. The rationale is that drug is a product with unavoidable risk and is a substantial beneficial product to the public, and the manufacturer can escape from strict liability if the producing procedure is qualified and the disclosure of information is complete. The defense of unavoidably unsafe products of drug is acceptable by the public.

The development strict liability of product in the United States has been a long process of legal history. Many principles like 1) transfer the burden of evidence on consumer to prove the negligence of producer to proving the existence of defect on products released by the producer, 2) punitive damages, it overcome the limitation of remedy based on traditional contracts or torts, 3) the consideration about public policy in the judicial decisions about harm to public health cases—Thalidomide and DES. These developments are influential not only in the United States, but also in many countries in the world.

## **b.**

After 1960s, courts were increasingly faced with defective design claims, and since the early 1980s these have formed the overwhelming bulk of product suits in America. Opponents also inserted that too extreme strict liability of products will harm American economy and eventually the public. In 1970s, some judicial decisions led to a dilemma—no necessary vaccines available, because the producers wanted to avoid strict liability of products. The eventual result of these factors was the Model Uniform Product Liability Act 1979 (MUPLA). Another concern during 1980s to 1990s was whether American companies lost their competition in international market? These kinds of arguments have even been lasting into the present (note 8).

## **C.**

The strict liability of products in Taiwan is based on the Consumer Protection Act (C.P.A.). C.P.A. # 7 explicitly reveals the manufacturer of product should make sure his products without the possibility to cause damage to life, body, health, or property of the consumer (subsection 1). If the product exists the possibility to cause damage to life, body, health, or property of the consumer, the manufacturer should express warning labeling clearly and the treatment for emergency (subsection 2). C.P.A. # 51: the consumer can claim no more than three times the amount of damage as punitive damage if the damage is caused by the subjective intention of manufacturer; the consumer can claim no more than one time the amount of damage as punitive damage if the damage is caused by the negligence of the manufacturer



C.P.A. was enacted in 1994 in Taiwan. It was a turning point for the right of consumers. Under the traditional law of torts, the plaintiff needs to prove the negligence of the manufacturer. In modern society, it is nearly impossible for a consumer to prove the negligence in the producing process of products. Consumers lack scientific knowledge, access to the manufacturer, money, and time. But based on the new law, like consumers in America, they only need to prove the existence of defect of products, and the defect leads to damage of life, body, health, or property, etc. The law is a big step in promoting the public benefits.

Of course, the new law also brings new debates. The most controversial issue is the conflict between subsection (3) of C.P.A. # 7 and the administrative regulatory rule # 5—the defense of scientific limitation. Some authors insist that the manufacturer can avoid any liability if he can prove the defect of products due to scientific limitation; some authors insisted that even though the manufacturer can succeed in defense of scientific limitation, it is just for the court to reduce the amount of remedy. It is really a dilemma to decide, not only from the aspect of consumer protection, but also from the aspect of industrial development and national policy. In the limited field of pharmaceuticals, there already are many factors to be considered:

**1.**

Unlike other industrial products, many drugs (especially prescription drugs) have known unavoidable risks to human bodies. These risks exist even under accurate and professional administration. If the law requires drugs to qualify Consumer Protection Act # 7 and at the same time does not allow the defense of scientific limitation or unavoidably unsafe products, no pharmaceutical companies can survive. The C.P.A # 10 also requires the manufacturer withdraw all risky products which violate C.P.A. # 7. If the judicial system does not allow the defense of scientific limitation or unavoidably unsafe products, consumers will find that they can not use most of drugs when they wake up tomorrow morning.

**2.**

In the past decades, many vaccine manufacturers have ceased their business because of no economic incentives. The prices of many vaccines have risen many times. In other aspects, the prices of new drugs have increased, too. The increased prices of vaccines and new drugs implied that in some poor families, children are more reluctant to receive the benefits of these treatments. It means children may die of diseases because of no money.

**3.**

The benefit of strict liability on drug is that the manufacturer would be more cautious in the development of new drug. This can avoid similar disasters in Thalidomide and DES. Nevertheless, the detriment is that consumers are more and more reluctant to new drugs. The lags of new drugs in the past three decades are more prolonged. At the same time, with the increasing cases of cancer, AIDS, or other serious diseases, people are eagerly to look forward to new treatments. Shortening the lag may save hundreds of thousands of lives per year. It is really difficult to decide the line between benefits and detriments.

#### 4.

As a newly industrialized country, Taiwan wants to encourage the development of pharmaceutical and biotechnological industries. If the strict liability of drugs require the manufacturers to cover the damage in the circumstances that the defense of scientific limitation can succeed, maybe no manufacturers would invest to do the R&D of new drugs. Some researches have end in this conclusion. Even in the United States, in Japan, and in Europe, the strict liability of drug is not so extremely. I don't think the extremely strict liability of drug is suitable in Taiwan.

### **The Conclusion**

Based on the analysis above, my opinion is that strict liability of drug should be limited. At the same time, in order to avoid debates and uncertainty, it is better to amend the Consumer Protection Act. The method is to add the clause of defense of scientific limitation or unavoidably unsafe products into the C.P.A. itself, instead of putting it in the administrative regulatory rules.

Of course, not only in Taiwan, but also in any other country in the world, the defense of scientific limitation or unavoidably unsafe products is always one of the most disputable issue in the strict liability of products. What kinds of drugs are recognized as unavoidably unsafe products and are exempted from strict liability? In the United States, some principles expressed in *Kearl v. Lederle Laboratories* (note 9) could be used as the basis for judgement: 1) whether the drug can provide substantial benefits to the public; 2) whether the risk is substantial and unavoidable; 3) whether the benefit of the drug is greater than the benefit under the strict liability of product. If the drug can pass the review of judge and jury, it can be deemed as an unavoidably unsafe product.

Does intravenous iodine-contained contrast medium belong to an unavoidably unsafe product? First, it is a very useful diagnostic drug. Without the help of it, many radiographic examinations like I.V.P., arthrography, angiography, and other invasive examinations are impossible to perform; without it, the accurate diagnosis in most cases of CT scans is impossible; without it, a radiologist is like losing his right hand. It has not toxicity to human body. Several hours after injection, it can be eliminated through urine without risk of accumulation in body. No other drug in the market can provide so many benefits like it to the patients. Second, the severe anaphylatic shock or death caused by it is really rare, and these reactions are due to idiosyncrasy of the patient himself. These reactions are unpredictable and unavoidable in the injection procedure. These risks are well-known, and if happen, doctors can provide emergent treatments. Before

injection of contrast medium, patients are required to sign an agreement, and at the same time are informed the unavoidable risk of this drug. Third, if this drug does not be recognized as an unavoidably unsafe product, that means it is under the strict liability of products. The incredible high insurance expenses and punitive damages would draw these pharmaceutical companies into bankruptcy, or the price of this drug would rise to an unacceptable status. Few people can afford it. Only few patients can get the accurate diagnosis needed for their clinical treatment plans. Many patients would die. On the other hand, allowing this drug to stay in the market actually did cause very few patients' death, but many more patients can benefit from it. The benefit is greater than the benefit of putting it into strict liability of products. According to the analysis, iodine-contained contrast medium should be recognized as an unavoidable unsafe product.

### III. THE LIABILITY OF THE DOCTOR

In cases of damages caused by drugs, the doctors are those who face patients or families most directly and closely. What kinds of liabilities should doctors take in the cases of damages caused by drug? Like the case above, does the radiologist have liability to the death of patient because the patient's idiosyncrasy to contrast medium? Does doctors should have strict liability? These questions are deserved analysis.

#### A.

##### 1.

In the past, doctors in Taiwan were rare challenged by patients, even in medical malpractice cases. Traditionally, doctors are quite respected by their patients. Patients also have little medical knowledge to question their doctors. Nevertheless, in the past decade, the litigation of medical malpractice cases has been rapidly increased. The liability of doctor in medical malpractice cases has also been discussed widely.

##### a.

In Taiwan, the relationship between a doctor and a patient is deemed as the contractual relationship. Doctors practicing in clinics or hospitals during office hours are deemed as giving their offers by facts, and the patients visiting them are deemed as accepting the offers. The contract between a doctor and a patient is classified as

a kind of model contract—contract of mandate in the Civil Code. This kind of contract implies with personal reliance of a patient toward a doctor. According to the Civil Code # 540, the doctor should inform the patient the associated issues. The Medical Treatment Act # 46 also expresses that a doctor should inform the patient of risks, side effects, adverse reactions, and reasons of treatment, and request the patient to sign the agreement. It is no doubt that the duty of informed consent is the basis of reliance relationship between a doctor and a patient.

In the administration of drug, the doctor should inform the patient of method of giving, dosage, side effects, adverse reactions, reasons, etc. In some special circumstances, for those drugs with higher incidence of severe adverse reactions like penicillin or contrast medium, informed consent will be given by documents.

#### **b. Duty of professional qualification**

After graduated from medical schools, medical students are required to pass the national license examination to practice medicine. But this qualification is an administrative registration, there is no absolutely relationship with whether a doctor commits a medical malpractice. The standard for judging whether a doctor qualified professional qualification is the objective standard in his professional society. A doctor should at least have the same abilities of his ordinary colleagues in medical society. In the process of giving drug to treat a patient, a doctor should judge the risks and benefits of different drugs and the characteristic history of the patient to give the most adequate regimen. For example, if a patient has the history of penicillin allergy, a doctor should avoid giving the patient drugs within penicillin group. In the case of contrast medium, some patients like victims of asthma, multiple myeloma, or renal insufficiency, should avoid ionic contrast medium; at this situation, a doctor should recommend the patient to use non-ionic hydrophilic contrast medium in order to reduce the possibility and severity of adverse reaction.

#### **c. Agreement of the patient**

The agreement of the patient is closely associated with the duty of informed consent by doctor. Many drugs have unavoidable adverse reactions and risks, the duty of informed consent require the doctor by his professional judgement to explain them to the patient. These treatments could cause damage to health, so the patient has the right to decide whether he is willing to take the risk and to burden the damages caused by the drug. If damage does happen, this agreement frees the liability of the doctor within the agreement. Nevertheless, the patient's agreement does not allow the doctor escape the liability due to negligence or intention. For example, even though the patient agrees to accept intravenous contrast medium, this agreement only let the doctor to escape the damage caused by unpredictable adverse reactions. In other words, if the doctor makes a mistake in the injection process and ruptures the patient's vessel, leading to ulceration due to accumulation of contrast medium in soft tissue, the doctor still have to take the liability due to medical malpractice. It is reasonable that the patient's agreement is not limitless.

#### **d. The duty of the doctor in medical malpractice**

If a doctor commits a medical malpractice, he would face civil responsibility first. The contractual relationship between a doctor and a patient is deemed as a contract of mandate. According to Civil Code # 535, the doctor should take the highest standard of duty of care—*culpa levis in abstracto*, a civil law principle originating from ancient law of Rome. It means that at least the doctor should have the average professional skills compared with his peers. Based on the contract of mandate, the doctor has liability of remedy. Another legal right for the patient to claim in a medical malpractice case is the right based on tort. Human body, health, and life are legal rights protected by civil law, so the doctor who harms a patient in a medical malpractice case is a tort. According to Civil Code # 184, # 192 to # 195, the doctor should cover the patient's damage including expenses, loss of benefits (salary or earnings), and spiritual damages. The plaintiff can choose one of these two claims (based on contract of mandate or based on tort) in the civil procedure.

One disputable issue in a medical malpractice case is whether the doctor should face the criminal punishment if the patient dies or has a body damage due to the doctor's negligence. The Criminal Law in Taiwan does punish body damages caused by negligence of doctors. The opinions against criminal punishment are 1) medical procedure is a kind of unavoidably high risk job; 2) no medical treatment can guarantee the good result; 3) from the view of social economic analysis, putting doctors into a jail is a loss to the public. The opinions for criminal punishment are 1) other professionals like drivers and pilots, they also work high risk jobs, and they can not be exempted from criminal punishment. Doctors can't be exempted, either; 2) if doctors can escape criminal punishment, it will encourage unnecessary opportunism of doctors; 3) civil liability and criminal punishment are two different areas. Each has its own different functions and principles, and no one can replace each other; 4) in judicial system, courts are very cautious in putting doctors into a jail in medical malpractice cases.

These debates have lasted for many years. Of course, medical professionals are against criminal punishment and the public is for criminal punishment. In the present criminal law system, doctors can not be exempted from criminal punishment. It can push doctors to take more cares in medical procedures. At the same time, as expressed above, the courts are very cautious in putting doctors into a jail in medical malpractice cases, and try to keep the fairness of criminal punishment and the welfare of the public.

e. Does strict liability apply to doctors—the disputes about Consumer Protection Act in Taiwan

In Taiwan, the Consumer Protection Act includes services in strict liability. It means a service should make sure that there is no risk to consumers. This clause induces very hot disputes in Taiwan. Only *two countries* (note 11) except Taiwan in the world promote the liability of services up to the standard of strict liability of products. Many legal researchers object this clause. I think this clause is a mistake in legislative process. During the hearing process in Congress, some interest groups and some politicians with certain intentions put lots of pressure upon many congressmen, and finally the law was distorted.

In the analysis of characteristics, services, especially medical services, are totally different from industrial products. First, unlike products, services can not be provided by a uniform manufacturing procedure. In industry, they can control the model, quality, and characteristics of these products. In medical services, every patient is a unique entity. A doctor who treats a patient needs to take the patient's history, sex, age, and other factors into his consideration. No uniform medical service can be made. Second, industrial

products can be mass-produced and sold in the market. A manufacturer can get lots of economic benefits by selling these products. The relationship between a service provider and a consumer is often based on personal reliance on professional ability. A service provider can not get lots of economic benefits by providing uniform services. Third, a manufacturer can more easily estimate the expense in covering the damages caused by his products. The loss can be distributed to the public by product liability insurance. A service provider, especially a medical professional, he faces too many unavoidable risks. It is sometimes difficult to estimate the risk in insurance policy. Fourth, many manufacturers, like pharmaceutical companies, are economic giants. They have the economic ability to cover the damages of victims caused by drugs. They should have more social duties to take care the damages due to usage of their products. For a medical professional, his economic ability is limited, and sometimes he can not fully cover the damages of a patient.

This dispute issue is a typical example of extreme invasion by interest groups in legislative process. At first, the public does not realize the detrimental residuals of this clause, and some politicians just want to appeal people. Let's suppose if strict liability applies to some jobs of high risk, like medical treatment, the public would be the final victims. Under strict liability, doctors will do more conservative treatments, because doctors want to protect themselves. The expense in medical treatment will be very high because doctors need to pay high insurance fees. Medical science will regress because few excellent professionals want to stay in this job. From the view of justice of law, it is also unfair to put so many burdens and unpredictable liabilities on doctors. Finally, the public will be the loser.

Services are in essence different from products. In America, services are not deemed suitable for strict liability of products. In *Gargne v. Betran* (note 12), the court explicitly revealed his opinion against putting service within the domain of the strict liability of products. In Taiwan, courts are also reluctant to give the plaintiff the verdict based on strict liability of service. In other words, courts are reluctant to apply this disputable clause in claims based on strict liability of services. The judgements of courts are according to the objective professional ability in the professional societies to testify whether there is negligence of professionals. If the defendant fails to qualify the standard, he is deemed with negligence. If his management is qualified with no evidence of negligence, or his defense of scientific limitation is accepted by the court, he is exempted from any liability. I agree with these judgements.

## 2.

### a. Duty of informed consent

In the early mentioned case—*Smith v. ER Squibb & Son*, the manufacturer didn't fully reveal clear and necessary warnings, and the doctor did not explain the risks to the patient. The court's opinions was 1) the pharmaceutical company should take the strict liability of products due to product defect because they did not well inform the risks of products; 2) the doctor should take the liability based on negligence—the tort, because he did not satisfy the duty of informed consent.

What is the difference between the liability of the doctor and the pharmaceutical company? I think it at least exists some important differences: 1) The burden of evidence—for the liability of negligence of the

doctor, the victim take the burden to prove the doctor neglect his duty; for the strict liability of products of pharmaceutical company, the patient just needs to prove the existed defect of product. 2) The difference in remedy—for the liability based on negligence, the doctor needs to cover the patient’s damage based on contract or on tort. No punitive damage will be granted. For the strict liability of products, the pharmaceutical company not only has to cover the patient’s damage, but also has to pay the patient based on punitive damages. 3) The pharmaceutical company is often an economic giant, it has more ability to fully cover the damages of the patient. From the view of social policy, it is more suitable for it to take the responsibility.

**b.**

In Anglo-American law, for the standard of professional qualification of doctor, courts have developed some principles. In *Bolan v. Friern Hospital Management Committee (1957) 2 All ER 118*, the court inserted that the professional standard for practicing doctors is not the standard for a reasonable man, the man on the Claphan omnibus, but the ordinary competent man in comparison with his peers in his professional society. In another case, *Blair v. Eblen, 461 S.W.2d 370, 373 (Ky. 1970)*, the court said: A physician is under a duty to use that degree of care and skill which is expected in reasonably competent practitioner in the same class to which he belongs, acting in the same or similar circumstances. . . . The evidence may include the elements of locality, availability of facilities, specialization or general practices, proximity of specialists and special facilities as well as other relevant consideration.

I think that there is no much difference in the standard adopted for negligence of doctors between Anglo-American law and civil law countries. These standards are all reasonable and objective.

### **III. THE ROLE OF ADMINISTRATIVE AGENCY**

The role of administrative agency in regulation of drugs is very important. Due to some historical tragedies, such as Thalidomide, DES, and tetracycline, the administrative agency in every country is cautious about the approval process of sale of drugs. What kind of factors do they need to take into consideration before the drug is allowed to sell in the market?

**1.**

In Taiwan, the administrative agency in charged of regulation of drug is Department of Health (DOH), and the most important associated law is the Drug Act, enacted in 1970.

a.

According to the Drug Act and associated laws and rules, the approval process is a sophisticated process by DOH. The goal of regulation is to promote the public health and ensure the safe and accurate usage of drugs. In the decision-making process, the officers of DOH need to balance many factors.

First, DOH needs to classify the applied drug to decide which category the drug should belong to. For some drug, like morphine, cocaine, or other addictive drugs, according to the Drug Act # 11, DOH has special regulatory rules to prevent abuse. Some drug, like antacids, or common pain reliever, DOH will consider whether it is suitable to put it in OTC classification or not. For different classifications, the laws and DOH regulatory rules have different policies.

Second, the safety of drug is always the main concern of DOH. Addictive drug like morphine or drugs with narrow safety margin and toxicity like digoxin, DOH has stricter regulation in production, marketing, sale, and clinical use. In the abuse circumstances, these drugs can cause serious adverse effects to human bodies. The abusers will be punished by criminal laws.

Third, the effectiveness of drug is also a main concern of DOH. The composition, effectiveness, and pharmacokinetics of drugs are all concerned by DOH. Adulterated drugs, or drugs without proven efficiency is banned by DOH.

Fourth, the advertisement of drugs is limited. The strict regulation of drug advertisement is often conflicted with the right of freedom of speech protected by Constitution. In Taiwan, like other countries, DOH faces these disputes. In 1996, the number 414 interpretation of constitution by the Supreme Court of Taiwan revealed the decision: The advertisement of drug is closely associated with the public health and social policy. In order to protect the interests of the public, it is constitutional to regulate the drug advertisement with a stricter standard. The Drug Act # 105 requires pre-marketing regulation of drug advertisement is the necessary method to improve the interests of the public, and does not conflict with Constitution.

Fifth, the consideration of cost and benefit of a drug. DOH always considers the cost and benefit of a drug in its regulation. Digoxin, a very effective drug in the treatment of cardiac disease, was approved even though it can cause toxicity. Morphine, a dangerous addictive drug, is allowed to use under closely supervision, because it has tremendous pain-relieving effect and sedative effect in terminal patients of cancer. Intravenous contrast medium, though it has unavoidable adverse reactions, DOH allows its use because of its irreplaceable diagnostic efficiency.

Sixth, the social policy is another important concern in decision-making of DOH. In some particular circumstances, DOH will allow usage of certain new drugs without regular approval process. About one-decade ago, there was very few effective drugs to treat AIDS. DOH allowed AZT in Taiwan and provides registered AIDS patients with free AZT treatment. From the view of public health, DOH wanted to encourage AIDS patients to register to DOH, and hope to eliminate the spreading of AIDS in Taiwan by providing free treatment.



The regulation of drug has never been a simple procedure. It has close relationship with the health and interests of the public. The role of DOH is more and more important because the more and more complicated technical and ethic issues after the rapid development of biotechnology and pharmaceutical industry.

**b. The difficulty in decision-making of administrative agency**

Sometimes, DOH will face a dilemma in decision making. Conray, a brand name of a kind of intravenous contrast medium, is an ionic iodine compound. It is a very good contrast medium with reasonable price. The drawback of Conray is that its incidence of adverse reactions is higher than some other non-ionic ones, for example, Isovist (brand name). Nevertheless, Isovist is three times more expensive than Conray. Should DOH ban the use of Conray? If all the patients in radiographic examinations use Isovist, the budget of National Health Insurance Program will be unable to afford it. After a hearing from doctors and scientists, DOH reached a compromised decision. Based on medical research, patients with some particular diseases, such as asthma, blood diseases, heart diseases, renal insufficiency, and some systemic diseases are more vulnerable to adverse reactions of Conray. These patients are covered by insurance if they use Isovist. The other patients are covered only the price of Conray, but they can pay the difference to use Isovist if they want to.

From the above story, we can realize that when DOH makes a decision, the officers need to think over many factors, including a very important one—the money. It is reasonable, like the regulation of contrast medium, to consider the distribution of limited budget. Like the example of AZT, DOH considered the policy of epidemic prevention and emergent circumstances. Trying to find a balance between many factors is always a dilemma DOH should face with.

**2.**

America has a long and tremendous tradition in governmental administration of drug regulation. It has complete legal system in this field, too. Its policies have influenced many countries. At the same time, America is the largest pharmaceutical country in the world, so any regulation by FDA will greatly impact the operation of many pharmaceutical companies. It is impossible to realize the evolution of drug regulation without knowing FDA and its policies.

**a.**

The history of FDA can be traced back to 1862, from the creation of U.S. Department of Agriculture (USDA)(note 13). The first drug legislation of national regulation of all human drug was the 1906 Food

and Drugs Act. Another big step was the Federal Food, Drug, and Cosmetic Act of 1938, which first time introduce two concepts—adulteration and misbranding. In 1962, one important amendment authorized FDA the power to regulate individual premarket approval of safety and effectiveness of every new drug. The 1962 amendment (note 14) did bring a big impact not only to FDA, but also to pharmaceutical companies due to premarket approval—the most important and controversial activity of FDA.

During 1950s to 1960s, the disaster of Thalidomide spread all over the world, but thanks to the strict regulation of FDA, America escaped the tragedy.

The effectiveness of a drug also has been regulated by FDA after 1962 Amendment of the FD&C Act. According to FD&C Act # 505 (d): Substantial evidence that the drug will have the effect it purports or as presented to have under the conditions of use described, recommended, or suggested in the proposed labeling. After 1962 Amendment, FDA has great power to play as a safeguard for the safety of Americans in the use of drugs.

**b.**

In the regulation of drugs, FDA will take many factors into consideration. In 1964, George Larrick, the FDA Commissioner, revealed the decision-making process of FDA in hearings before a Subcommittee of the House Committee on Government Operations. In his famous three-step operation, he said: Step 1. Determine the benefit to be derived from the drug; Step 2. Determine the risk; and Step 3. Weigh the benefit against the risk and decide whether it is in the public interest to approve the drug for marketing or to withdraw approval if the product is already on the market (note 15 ).

In the approval a new drug, for example, FDA shall consider its safety (Section 505(d) of FD & C Act); In the same Section, FDA shall require the sponsor provides substantial evidence that the drug will have the effect it purports or. . . .

In the public interest and social policy aspect, FDA will check balance between risk and benefit. In the epidemic of AIDS, FDA for the first time, announced an official expedited approval of new drugs for life-threatening and severely debilitating diseases. In this so called the AIDS revolution, FDA showed its dilemma in decision-making process while facing with safety, effectiveness, risk evaluation, and even political pressure from different interest groups.

Another important factor that will shape the regulation of FDA is the opinions from the pharmaceutical industry. Because every step of FDA will greatly influence the R & D of these pharmaceutical companies, they are really concerned what FDA will adopt. In other words, FDA's steps will greatly influence the economy of American pharmaceutical industry. At the same time, these companies also always challenge FDA by litigation, political lobby, and research results.

The decision-making of FDA is a highly complicated and sophisticated process. Too many factors should be taken into consideration. Sometime it is hard to decide what is right or what is wrong, and only the time can tell the answer.

### **c. The dilemma of America**

Since 1960s, two great evolutions—the 1962 Amendment and strict liability of products have change the drug regulation and liability of damages caused by drugs. The benefits brought by these two changes are 1) consumers can use safer and more effective drugs; 2) pharmaceutical companies are more careful in the development of new drugs; 3) the public can avoid unknown and prolonged adverse reactions of drugs.

Nevertheless, they also have brought big impacts on the public and pharmaceutical companies. As a regulatory agency, FDA may become conservative in approval of a new drug. It is a natural charisma of FDA—FDA Risk Aversion (note 16). The result is the Drug Lag. In his research, Professor Sam Peltzman revealed: It is beyond dispute that new drug innovation in the United States has declined since 1962. And he concludes that The benefits provided by the amendments seem clearly out-weighed by the costs they have engendered. . . . As I hope to make clear, consumers could not have avoided losses under the most efficient and well-intentioned administration of the law. . . . According to the research by Professor Milton Friedman, the time and expenses needed in the R & D of a new drug had jumped many times since 1950s to 1970s. To those pharmaceutical companies, it means that they may loss their competition in the international market. As the largest pharmaceutical country in the world and the leading country in pharmaceutical technology, the impacts are huge. Strict regulation can drag the development of industry and delay the new drugs expected by patients with incurable diseases. The balance between risk control of drugs and economic benefits of pharmaceutical industry is always a difficult issue in America.

### **3. Conclusion**

The regulation of administrative agency is a necessary part in drug development. In comparison with other products, drugs are needed to pass strict premarketing approval. It is the lessons of some historical tragedies. In Germany, the Thalidomide incidence led to a series of reviews and legislation. These kinds of efforts happened in many countries, too. It seems to work, because big disaster like Thalidomide incidence never happens again. But too strict regulations also bring some side effects, like drug lag, expensive drugs, and delayed availability of drugs for emergency or serious diseases. The balance between different factors is always the dilemma for administrative agency.

## **IV. THE TENDENCY IN THE DEVELOPMENT OF COMPENSATORY SYSTEM IN DAMAGES CAUSED BY DRUGS**

The development of strict liability of products have provided the victims suffering from defects of products with an easier way to cover their damages. In compliance with this system, what is the best way to cover the damages of patient, and what is the best way to distribute the risk of loss, are unavoidable issues associated with strict liability of products. In come circumstances, like the patient with idiosyncrasy suffering by injection of contrast medium, can not cover his damage if the producer succeed in the defense of unavoidably unsafe products. Is there any other method to cover the damage of the patient?

**1.**

Under the strict liability of products, for the victims, they are most concerned about the full-coverage of damages, and for the defendants, they are most concerned about the distribution of risk of loss. In other words, without the associated systems, for example, like the liability insurance, the strict liability of products will lose its function.

**a.**

The goal of insurance for strict liability of products is that the producer can reasonably allocate the loss to every consumer. It means that the damages of certain victims can be distributed to all the consumers and the insurance can cover the loss of the producer. The producer pays the insurance fees; the insurance company covers the loss of the producer if strict liability of products happens; and the insurance fees will be transferred into the cost of products, so can be distributed to all the consumers by elevating the price of the product.

Let's take intravenous contrast medium as an example: Because the incidental-rate for adverse reactions of contrast medium is well-documented in medical researches, the insurance company can estimate the fees. The pharmaceutical company can internalize the fees into costs of products and distribute the expense to all the patients using this drug by reasonably rising its price. If damages happen, and the producer is judged by the court to take the strict liability of products, the loss of the producer can be covered by the insurance.

The problem is—in some circumstances, the damages caused by drugs won't be discovered until many years later. Tetracycline, Thalidomide, and Tetracycline are most famous ones. Faced with these unknown rather than uncertain risks, how does the insurance company estimate the insurance fees? It is really an unsolved problem to producers and insurance companies. The result may be that no insurance company wants to accept the liability insurance of a new drug. Another side effect is that a GMP pharmaceutical company with traditionally good reputation can go bankrupt in a short period of time.

Another shortcoming in liability insurance is the cost and time-consuming process in litigation for the victims. For many victims, their job, family, and health is sucked into a crisis. What they need is a rapid relief for their emergencies. The prolonged judicial process is another torture to them in some aspects. This is the limitation of strict liability of products.

**b.**

Is it a proper way for doctors to take the expense of insurance for strict liability of drugs? I think there are many reasons that doctors are not suitable to be the ones who take the risk:

First, the drug causing damages is produced by the pharmaceutical company, not by the doctor. The pharmaceutical company can get lots of economic benefits from the drug. It is reasonable to allocate the risk of loss to the one who received benefits before.

Second, a doctor may use thousands of drugs to treat his patients. If a doctor should take the strict liability of every kind of drug, the duty is too heavy for any doctor. The insurance fees will be incredible high for a doctor, and I believe no doctor can afford it. On the contrary, a pharmaceutical company is easier to estimate the insurance fee and can distribute the risk to its products efficiently.

Third, strict liability is based on risky products, not based on service. Doctors only provide services by using the products—the drugs. If a doctor does not have negligence in his professional skills, he has no duty to take the liability due to defects of drugs. For doctors, what they should consider is the liability insurance for medical malpractice, rather than the strict liability of drugs.

Fourth, financially, no doctor can compete with a big pharmaceutical company. In the aspect of satisfying the coverage of damages, a doctor is not a suitable one. If a doctor faces multiple victims, it is quite possible that every patient only can get very little amount of money. For the condition of pharmaceutical company to take the liability, victims are easier to get full coverage.

According to the analyses above, doctors are not suitable to take the duty to take part in the insurance for strict liability of drugs.

## **2.**

As mentioned above, in circumstances that the producer can defend successfully with unavoidably unsafe product or scientific limitation, or in circumstances that the damages happen due to patients' idiosyncrasy, how can victims get compensation? In these conditions, should other systems, like social welfare step in?

Many countries have developed direct compensation system to cover the damages of victims caused by drugs. The goal of direct compensation is to rapidly cover the damages of patients, and to avoid the prolonged judicial process. These kinds of systems have many characteristics of social welfare system, and are designed to distribute the risk to all the citizens.

### **a.**

–America: In 1986, Congress enacted the National Childhood Vaccine Injury Act of 1986. This Act creates a no-fault compensation system by a particular foundation. The supply of the foundation is based on an excise tax levied on vaccine sales. Compensation is payable if a child experiences specified symptoms or reactions caused by vaccination (note 17).

This Act has some implied public health policies: 1) after a series of strict liability cases (note 18), fewer and fewer pharmaceutical companies had intention to get involved with the vaccine production. The federal government wanted to encourage pharmaceutical industry to invest in vaccine production; 2) the effectiveness of vaccination needs to reach a threshold in number, the Act can encourage patents to let their children to receive vaccination; 3) as the comment by Professor Hutt, the 1986 Act appears to respond at least in part to the need for a Federal insurance program to cover the damages caused by vaccines.

With regard to the compensation system for other drugs, there is no system like the above Act.

–**Germany:** Being a country encountered with the most severe damages in Thalidomide disaster, in 1970s, Germany developed an unique system combined with liability of product and compensation system based on foundation to cover the damages caused by drugs. The function of this foundation is to cover the patients who can not get the remedy through litigation.

–**Sweden and Finland:** The pharmaceutical insurance schemes have been existing in Sweden and Finland since 1978 and 1984, respectively. The schemes complement a system of Patient Insurance for injuries arising in the course of medical treatment. The money needed for operation is from levies or premiums form pharmaceutical industry. Under this system, unexpected drug reactions will in most circumstances be compensated. Sweden and Finland are both socialism countries, so this system is also full of characteristics of social welfare (note 19).

–**Japan:** While has not yet adopted comprehensive no-fault product liability for damages caused by drugs, Japan has two Acts to partially cover the victims. The first one is the Vaccination Act (1976) which provides for compensation to families of children harmed by compulsory vaccination. The other is Adverse Drug Reaction Injury Relief and Research Promoting Fund Act (1979). According to this Act, a foundation was established to provide prompt compensation for patients caused by drugs. In the event the suit is successful, then the prepaid money is returned to the foundation.

## 2. The Present Development in Taiwan

In 1992, DOH of Taiwan announced a regulatory rule to compensate the victims caused by compulsive vaccination. The financial origin is from the tax levied from the vaccine producers or importers. Victims can apply for compensation from DOH, where a committee will review the application.

In January 1999, DOH enacted another regulatory rule—the Method for Compensation of Victims of Drugs. According to this rule, pharmaceutical companies will donate 0.1 % of their annual amount of sales to form a foundation. The victim can get prompt compensation with upper limit of two million Taiwanese dollars,

about equal to sixty-five thousand of US dollars. It is a compensation system to cover the damages while the victim, the doctor prescribing the drug, and the producer are all with no fault.

It is obvious that Taiwan was delayed in the compensation system in damages caused by vaccination. The new compensation system that covers all the prescription drugs and OTC drugs is a big step in Taiwan.

## V.

The evolution of liability of drugs is a long history. In the beginning, victims only can cover their damages based on traditional contract law and torts law. With the effort of courts, the victims gradually overcome the limitation of contracts and torts. In 1960s, the theory of strict liability of products greatly changed the way the victims can recover. The burden of evidence on plaintiffs to insert the negligence of producers transferred to the duty to prove existed defects of products and damages caused by products. These changes put the burden on the defendants to prove their no-fault. The defendants only can escape the strict liability of products by successful defense of unavoidably unsafe products or scientific limitations. Associated with strict liability of drugs, insurance of liability developed. The system was designed to distribute the risk to all the consumers. In some circumstances, like damages due to idiosyncrasy of the patient himself, the victim still can not get any remedy based on strict liability of drugs. In some circumstances, the victim was in economic emergence due to damages caused by drugs, and the long process of litigation is another torture to him. How to give the patient a help promptly? The compensation system for victims of vaccination is the first step in this kind of social welfare system. Then, in Sweden, Japan, Finland, and some other countries, there are some more expansive system to cover victims due to no-fault damages by drugs. This year, Taiwan also had the same system.

Another aspect of drug liability is associated with the regulation of administrative agency. From the lessons of Thalidomide, DES, Tetracycline, and many other drugs, administrative agency adopted stricter policies in drug regulation. These strict administrative regulations, for instance like premarketing approval of a new drug, did reduce the incidence of tragedy. But the associated side effects are drug lag, delayed availability of new drugs, increasing drug prices, and maybe death of patients due to lack of emergent drugs. Another aspect of strict regulation is the great impacts on pharmaceutical industry. Fewer and fewer pharmaceutical companies want to produce vaccines or to invest on R & D of new drugs. Sometimes, administrative agency will face a dilemma produced by itself.

The development of liability of drugs is a complicated and sophisticated process, like drugs. Intravenous iodine-contained contrast medium, a diagnostic drug with excellent effectiveness and unavoidable risks, can show the controversial characteristics in the development of drug liability and administrative regulation. Does the story end? I don't think so. Maybe another ten years, we can see some brilliant systems to solve these problems effectively.

## FOOT NOTES

1. *National Health Insurance Program*: This is a mandatory health insurance program in Taiwan. Every citizen is required to take part in this program, and government and citizens share the budget of the insurance program. So, the cost and benefit concern is always the important issue at spot.
2. *Gottsdankerv. Cuttler Labs.*, 182 Cal. 2d 602, 6 Cal. Rptr.320 (1960): The court delivered its opinion that the producer should take the responsibility to the accidents caused by polio vaccine, even though there is no direct contractual relationship between the victims and the producer.
3. *William L. Prosser, The Fall of Citadel, Strict Liability to the Consumer*, 50 Minn. Law Review. 791 (1965)
4. *Scientific limitation of iodine-contained contrast medium*: Until now, scientists haven't other compounds that can replace iodine-contained contrast medium with radio-opaque characteristic and without toxicity at the same time.
5. *MacPherson v. Buick Motor Co.*, 217 N.Y. 382, 111 N.E. 1050 (1916). Judge Cardozo said if danger was to be expected as reasonably certain, there was a duty of vigilance, and whether you call the danger inherent or imminent Derrick Owles & Anthea Worsdall, Product Liability Casebook-US and UK judgements and commentaries, p 4, Lioud's of London Press Ltd, 1984.
6. *Smith v. ER Squibb & Sons*: Derrick Owles & Anthea Worsdall, Product Liability Casebook-US and UK judgements and commentaries, p 46, Lioud's of London Press Ltd, 1984.
7. *Sindell v. Abbott Laboratories*: Derrick Owles & Anthea Worsdall, Product Liability Casebook-US and UK judgements and commentaries, p 52, Lioud's of London Press Ltd, 1984.
8. Jane Stapleton, Product Liability, p.29, published by Latimer Trend & Company Ltd.,1994
9. Steven Garber, Product Liability and the Economics of Pharmaceuticals and Medical Devices, p 144, RAND,1993
10. *Kearl v. Lederle Laboratories*, 172. Cal. App. 3d 812, 218 Cal. Rptr, 453 (1985)
11. China and Brazil: Both countries include services in strict liability.
12. *Gargne v. Betran*, 43 Cal.2d.481, 275 p.2d 15 (1954).
13. *Peter Barton Hutt & Richard A. Merrill, Food and Drug Law*, p.4, 1991
14. *Peter Barton Hutt & Richard A. Merill, Food and Drug Law*, p.13, 1991
15. *Testimony of George Larrick: Peter Barton Hutt & Richard A. Merill, Food and Drug Law*, p.522, 1991.



16. *FDA Risk Aversion: Peter Barton Hutt & Richard A. Merrill, Food and Drug law, p.582, 1991.*

17. *National Childhood Vaccine Injury Act of 1986: Peter Barton Hutt & Richard A. Merrill, Food and Drug Law, p. 718, 1991.* Under the act, the compensation is payable if a child experiences specified symptoms or reactions within stated time periods after vaccination and they persist for six months, unless the government can prove the injury was caused by some other event.

18. Peter Barton Hutt & Richard A.Merill, Food and Drug Law, p. 697 to 710, 1991.

19. Pharmaceutical Insurance in Sweden and Finland: see Trends in Product Liability Law and No-Fault Compensation for Drug-Induced Injuries, edited by Sheila R. Shulman & Louis Lassgan, published by The Ccenter For The Study of Drug Development, TuftsUniversity.

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